US009414918B2

(12) **United States Patent**
Chau et al.

(10) **Patent No.: US 9,414,918 B2**
(45) **Date of Patent: Aug. 16, 2016**

(54) **HEART VALVE SEALING DEVICES**

(71) Applicant: **Edwards Lifesciences Corporation**, Irvine, CA (US)

(72) Inventors: **Mark Chau**, Aliso Viejo, CA (US); **Travis Oba**, Brea, CA (US); **Sergio Delgado**, Irvine, CA (US); **Robert C. Taft**, Irvine, CA (US)

(73) Assignee: **Edwards Lifesciences Corporation**, Irvine, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 311 days.

(21) Appl. No.: **14/019,332**

(22) Filed: **Sep. 5, 2013**

(65) **Prior Publication Data**

US 2014/0067052 A1 Mar. 6, 2014

Related U.S. Application Data

(60) Provisional application No. 61/697,706, filed on Sep. 6, 2012, provisional application No. 61/763,848, filed on Feb. 12, 2013.

(51) **Int. Cl.**
A61F 2/24 (2006.01)

(52) **U.S. Cl.**
CPC ***A61F 2/2442*** (2013.01); ***A61F 2/246*** (2013.01); ***A61F 2/2454*** (2013.01); ***A61F 2/2463*** (2013.01); ***A61F 2/2466*** (2013.01); *A61F 2/2457* (2013.01); *A61F 2250/0003* (2013.01)

(58) **Field of Classification Search**
CPC A61F 2/2457; A61F 2/246; A61F 2/2463; A61F 2/2442; A61F 2/2418; A61F 2/2427; A61F 2/2436; A61F 2/2487; A61F 2/2409; A61F 2/2412; A61F 2/2439; A61F 2/2445; A61F 2/2454; A61F 2/2475
USPC 623/2.11, 2.26
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

3,409,013 A 11/1968 Berry
3,472,230 A 10/1969 Fogarty et al.
3,548,417 A 12/1970 Kisher

(Continued)

FOREIGN PATENT DOCUMENTS

DE 2246526 3/1973
DE 19532846 3/1997

(Continued)

OTHER PUBLICATIONS

Al-Khaja, N., et al., "Eleven Years' Experience with Carpentier-Edwards Biological Valves in Relation to Survival and Complications," European Journal of Cardiothoracic Surgery 3:305-311, Jun. 30, 2009.

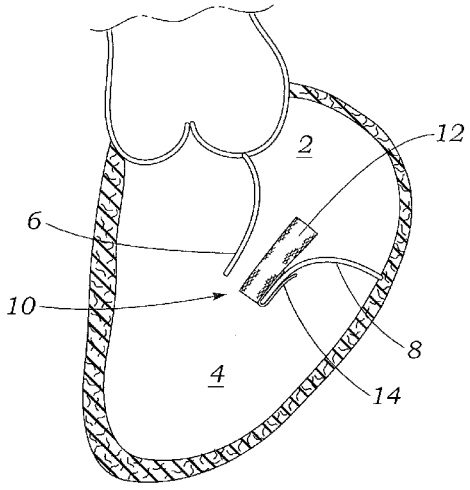
(Continued)

Primary Examiner — Jonathan Miles
Assistant Examiner — Erich Herbermann

(57) **ABSTRACT**

This disclosure pertains generally to prosthetic devices and related methods for helping to seal native heart valves and prevent or reduce regurgitation therethrough, as well as devices and related methods for implanting such prosthetic devices. In some cases, a spacer having a single anchor can be implanted within a native heart valve. In some cases, a spacer having dual anchors can be implanted within a native heart valve. In some cases, devices can be used to extend the effective length of a native heart valve leaflet.

5 Claims, 26 Drawing Sheets



(56) **References Cited**

U.S. PATENT DOCUMENTS

3,587,115 A 6/1971 Shiley
3,657,744 A 4/1972 Ersek
3,671,979 A 6/1972 Moulopoulos
3,714,671 A 2/1973 Edwards et al.
3,755,823 A 9/1973 Hancock
4,035,849 A 7/1977 Angell et al.
4,056,854 A 11/1977 Boretos et al.
4,106,129 A 8/1978 Carpentier et al.
4,222,126 A 9/1980 Boretos et al.
4,265,694 A 5/1981 Boretos et al.
4,297,749 A 11/1981 Davis et al.
4,339,831 A 7/1982 Johnson
4,343,048 A 8/1982 Ross et al.
4,345,340 A 8/1982 Rosen
4,373,216 A 2/1983 Klawitter
4,406,022 A 9/1983 Roy
4,470,157 A 9/1984 Love
4,535,483 A 8/1985 Klawitter et al.
4,574,803 A 3/1986 Storz
4,592,340 A 6/1986 Boyles
4,605,407 A 8/1986 Black et al.
4,612,011 A 9/1986 Kautzky
4,643,732 A 2/1987 Pietsch et al.
4,655,771 A 4/1987 Wallsten
4,692,164 A 9/1987 Dzemeshkevich et al.
4,733,665 A 3/1988 Palmaz
4,759,758 A 7/1988 Gabbay
4,762,128 A 8/1988 Rosenbluth
4,777,951 A 10/1988 Cribier et al.
4,787,899 A 11/1988 Lazarus
4,787,901 A 11/1988 Baykut
4,796,629 A 1/1989 Grayzel
4,829,990 A 5/1989 Thuroff et al.
4,851,001 A 7/1989 Taheri
4,856,516 A 8/1989 Hillstead
4,878,495 A 11/1989 Grayzel
4,878,906 A 11/1989 Lindemann et al.
4,883,458 A 11/1989 Shiber
4,922,905 A 5/1990 Strecker
4,966,604 A 10/1990 Reiss
4,979,939 A 12/1990 Shiber
4,986,830 A 1/1991 Owens et al.
4,994,077 A 2/1991 Dobben
5,007,896 A 4/1991 Shiber
5,026,366 A 6/1991 Leckrone
5,032,128 A 7/1991 Alonso
5,037,434 A 8/1991 Lane
5,047,041 A 9/1991 Sammuels
5,059,177 A 10/1991 Towne et al.
5,080,668 A 1/1992 Bolz et al.
5,085,635 A 2/1992 Cragg
5,089,015 A 2/1992 Ross
5,108,370 A 4/1992 Walinsky
5,152,771 A 10/1992 Sabbaghian et al.
5,163,953 A 11/1992 Vince
5,167,628 A 12/1992 Boyles
5,192,297 A 3/1993 Hull
5,232,446 A 8/1993 Arney
5,266,073 A 11/1993 Wall
5,282,847 A 2/1994 Trescony et al.
5,295,958 A 3/1994 Shturman
5,332,402 A 7/1994 Teitelbaum
5,360,444 A 11/1994 Kusuhara
5,370,685 A 12/1994 Stevens
5,397,351 A 3/1995 Pavcnik et al.
5,411,055 A 5/1995 Kane et al.
5,411,522 A 5/1995 Trott
5,411,552 A 5/1995 Andersen et al.
5,443,446 A 8/1995 Shturman
5,480,424 A 1/1996 Cox
5,500,014 A 3/1996 Quijano et al.
5,545,209 A 8/1996 Roberts et al.
5,545,214 A 8/1996 Stevens
5,549,665 A 8/1996 Vesely
5,554,185 A 9/1996 Block et al.
5,571,175 A 11/1996 Vanney et al.
5,591,185 A 1/1997 Kilmer et al.
5,599,305 A 2/1997 Hermann et al.
5,607,464 A 3/1997 Trescony et al.
5,609,626 A 3/1997 Quijano et al.
5,639,274 A 6/1997 Fischell et al.
5,665,115 A 9/1997 Cragg
5,716,417 A 2/1998 Girard et al.
5,728,068 A 3/1998 Leone et al.
5,749,890 A 5/1998 Shaknovich
5,756,476 A 5/1998 Epstein
5,769,812 A 6/1998 Stevens et al.
5,800,508 A 9/1998 Goicoechea et al.
5,840,081 A 11/1998 Andersen et al.
5,855,597 A 1/1999 Jayaraman
5,855,601 A 1/1999 Bessler
5,855,602 A 1/1999 Angell
5,906,619 A 5/1999 Olson et al.
5,925,063 A 7/1999 Khosravi
5,957,949 A 9/1999 Leonhardt et al.
5,968,068 A 10/1999 Dehdashtian
6,027,525 A 2/2000 Suh et al.
6,042,607 A 3/2000 Williamson, IV et al.
6,132,473 A 10/2000 Williams et al.
6,168,614 B1 1/2001 Andersen et al.
6,171,335 B1 1/2001 Wheatley et al.
6,174,327 B1 1/2001 Mertens et al.
6,210,408 B1 4/2001 Chandrasakaran et al.
6,217,585 B1 4/2001 Houser et al.
6,221,091 B1 4/2001 Khosravi
6,231,602 B1 5/2001 Carpentier et al.
6,245,040 B1 6/2001 Inderbitzen
6,245,102 B1 6/2001 Jayaraman
6,287,339 B1 9/2001 Vazquez et al.
6,299,637 B1 10/2001 Shaolian
6,302,906 B1 10/2001 Goecoechea et al.
6,306,141 B1 10/2001 Jervis
6,312,465 B1 11/2001 Griffin et al.
6,350,277 B1 2/2002 Kocur
6,379,372 B1 4/2002 Dehdashtian et al.
6,425,916 B1 7/2002 Garrison et al.
6,440,164 B1 8/2002 Di Matteo et al.
6,454,799 B1 9/2002 Schreck
6,458,153 B1 10/2002 Bailey et al.
6,461,382 B1 10/2002 Cao
6,468,660 B2 10/2002 Ogle
6,482,228 B1 11/2002 Norred
6,488,704 B1 12/2002 Connelly et al.
6,527,979 B2 3/2003 Constantz
6,569,196 B1 5/2003 Vesely et al.
6,582,462 B1 6/2003 Andersen et al.
6,605,112 B1 8/2003 Moll
6,730,118 B2 5/2004 Spenser et al.
6,733,525 B2 5/2004 Yang et al.
6,790,229 B1 9/2004 Berreklouw
6,830,584 B1 12/2004 Seguin
6,893,460 B2 5/2005 Spenser et al.
6,908,481 B2 6/2005 Cribier
6,974,476 B2 12/2005 McGuckin et al.
7,018,406 B2 3/2006 Seguin et al.
7,198,646 B2 4/2007 Figulla et al.
7,201,772 B2 4/2007 Schwammenthal et al.
7,276,078 B2 10/2007 Spenser et al.
7,276,084 B2 10/2007 Yang et al.
7,318,278 B2 1/2008 Zhang et al.
7,374,571 B2 5/2008 Pease et al.
7,381,210 B2 6/2008 Zarbatany et al.
7,393,360 B2 7/2008 Spenser et al.
7,429,269 B2 9/2008 Schwammenthal et al.
7,442,204 B2 10/2008 Schwammenthal et al.
7,462,191 B2 12/2008 Spenser et al.
7,510,575 B2 3/2009 Spenser et al.
7,524,330 B2 4/2009 Berreklouw
7,530,253 B2 5/2009 Spenser
7,579,381 B2 8/2009 Dove
7,585,321 B2 9/2009 Cribier
7,618,446 B2 11/2009 Andersen et al.
7,621,948 B2 11/2009 Herrmann
7,704,222 B2 4/2010 Wilk et al.

(56) **References Cited**

U.S. PATENT DOCUMENTS

7,736,327	B2	6/2010	Wilk et al.	
7,892,281	B2	2/2011	Seguin et al.	
7,914,575	B2	3/2011	Guyenot et al.	
7,993,394	B2	8/2011	Hariton et al.	
8,007,992	B2	8/2011	Tian et al.	
8,029,556	B2	10/2011	Rowe	
8,092,521	B2	1/2012	Figulla et al.	
8,118,866	B2	2/2012	Herrmann et al.	
8,167,932	B2	5/2012	Bourang	
8,206,437	B2	6/2012	Bonhoeffer et al.	
8,216,174	B2	7/2012	Wilk et al.	
8,317,858	B2	11/2012	Straubinger et al.	
8,398,704	B2	3/2013	Straubinger et al.	
8,407,380	B2	3/2013	Matsunaga	
8,416,643	B2	4/2013	Magee	
8,449,599	B2	5/2013	Chau	
8,778,017	B2 *	7/2014	Eliasen	A61F 2/246 623/1.11
2001/0021872	A1	9/2001	Bailey et al.	
2002/0032481	A1	3/2002	Gabbay	
2002/0173842	A1	11/2002	Buchanan	
2003/0050694	A1	3/2003	Yang et al.	
2003/0100939	A1	5/2003	Yodfat et al.	
2003/0130731	A1	7/2003	Vidlund	
2003/0158597	A1	8/2003	Quiachon	
2003/0212454	A1	11/2003	Scott et al.	
2004/0039436	A1	2/2004	Spenser et al.	
2004/0092858	A1	5/2004	Wilson et al.	
2004/0133263	A1	7/2004	Dusbabek et al.	
2004/0186563	A1	9/2004	Lobbi	
2004/0186565	A1	9/2004	Schreck	
2004/0260389	A1	12/2004	Case et al.	
2005/0137688	A1	6/2005	Salahieh et al.	
2005/0137698	A1	6/2005	Salahieh et al.	
2005/0203614	A1	9/2005	Forster et al.	
2005/0203617	A1	9/2005	Forster et al.	
2005/0234546	A1	10/2005	Nugent et al.	
2005/0288766	A1	12/2005	Plain et al.	
2006/0025857	A1	2/2006	Bergheim et al.	
2006/0058872	A1	3/2006	Salahieh et al.	
2006/0142837	A1	6/2006	Haverkost et al.	
2006/0149350	A1	7/2006	Patel et al.	
2006/0161249	A1	7/2006	Realyvasquez et al.	
2006/0195134	A1	8/2006	Crittenden	
2006/0229719	A1	10/2006	Marquez et al.	
2006/0241745	A1	10/2006	Solem	
2006/0259135	A1	11/2006	Navia et al.	
2006/0259137	A1	11/2006	Artof et al.	
2006/0276874	A1	12/2006	Wilson et al.	
2007/0005131	A1	1/2007	Taylor	
2007/0005231	A1	1/2007	Seguchi	
2007/0010877	A1	1/2007	Salahieh et al.	
2007/0027534	A1	2/2007	Bergheim et al.	
2007/0088431	A1	4/2007	Bourang et al.	
2007/0100439	A1	5/2007	Cangialosi et al.	
2007/0112422	A1	5/2007	Dehdashtian	
2007/0142906	A1	6/2007	Figulla et al.	
2007/0203503	A1	8/2007	Salahieh et al.	
2007/0203575	A1	8/2007	Forster et al.	
2007/0213813	A1	9/2007	Von Segesser et al.	
2007/0270943	A1	11/2007	Solem	
2008/0065011	A1	3/2008	Marchand et al.	
2008/0071361	A1	3/2008	Tuval et al.	
2008/0071362	A1	3/2008	Tuval et al.	
2008/0071363	A1	3/2008	Tuval et al.	
2008/0071366	A1	3/2008	Tuval et al.	
2008/0071368	A1	3/2008	Tuval et al.	
2008/0071369	A1	3/2008	Tuval et al.	
2008/0082166	A1	4/2008	Styrc et al.	
2008/0114442	A1	5/2008	Mitchell et al.	
2008/0125853	A1	5/2008	Bailey et al.	
2008/0154355	A1	6/2008	Benichou et al.	
2008/0161911	A1	7/2008	Revuelta et al.	
2008/0208328	A1	8/2008	Antocci et al.	
2008/0208332	A1	8/2008	Lamphere et al.	
2008/0221672	A1	9/2008	Lamphere et al.	
2008/0255660	A1	10/2008	Guyenot et al.	
2008/0255661	A1	10/2008	Straubinger et al.	
2008/0281411	A1	11/2008	Berreklouw	
2008/0288061	A1 *	11/2008	Maurer	A61F 2/246 623/2.36
2009/0005863	A1	1/2009	Goetz et al.	
2009/0048668	A1 *	2/2009	Wilson	A61F 2/2466 623/2.36
2009/0054968	A1	2/2009	Bonhoeffer et al.	
2009/0054974	A1	2/2009	McGuckin, Jr. et al.	
2009/0062908	A1	3/2009	Bonhoeffer et al.	
2009/0076598	A1	3/2009	Salahieh et al.	
2009/0112309	A1	4/2009	Jaramillo et al.	
2009/0138079	A1	5/2009	Tuval et al.	
2009/0157175	A1	6/2009	Benichou	
2009/0164005	A1	6/2009	Dove et al.	
2009/0171432	A1	7/2009	Von Segesser et al.	
2009/0171447	A1	7/2009	Von Segesser et al.	
2009/0171456	A1	7/2009	Kveen et al.	
2009/0216310	A1	8/2009	Straubinger et al.	
2009/0216313	A1	8/2009	Straubinger et al.	
2009/0216322	A1	8/2009	Le et al.	
2009/0222076	A1	9/2009	Figulla et al.	
2009/0234443	A1	9/2009	Ottma et al.	
2009/0240320	A1	9/2009	Tuval et al.	
2009/0276040	A1	11/2009	Rowe et al.	
2009/0281619	A1	11/2009	Le et al.	
2009/0287299	A1	11/2009	Tabor et al.	
2009/0319037	A1	12/2009	Rowe et al.	
2010/0016958	A1	1/2010	St. Goar et al.	
2010/0049313	A1	2/2010	Alon et al.	
2010/0131054	A1	5/2010	Tuval et al.	
2010/0137979	A1	6/2010	Tuval et al.	
2010/0174362	A1	7/2010	Straubinger et al.	
2010/0204781	A1	8/2010	Alkhatib	
2010/0217382	A1	8/2010	Chau et al.	
2010/0262231	A1	10/2010	Tuval et al.	
2011/0015616	A1	1/2011	Straubinger et al.	
2011/0015729	A1	1/2011	Jimenez et al.	
2011/0137397	A1	6/2011	Chau et al.	
2011/0208290	A1	8/2011	Straubinger et al.	
2011/0208297	A1	8/2011	Tuval et al.	
2011/0208298	A1	8/2011	Tuval et al.	
2011/0238159	A1	9/2011	Guyenot et al.	
2011/0288634	A1	11/2011	Tuval et al.	
2011/0319989	A1	12/2011	Lane et al.	
2012/0035722	A1	2/2012	Tuval et al.	
2012/0046741	A1	2/2012	Tuval et al.	
2012/0046742	A1	2/2012	Tuval et al.	
2012/0101570	A1	4/2012	Tuval et al.	
2012/0123529	A1	5/2012	Levi et al.	
2012/0185039	A1	7/2012	Tuval et al.	
2012/0197386	A1	8/2012	Von Segesser et al.	
2012/0209374	A1	8/2012	Bonhoeffer et al.	
2012/0283823	A1	11/2012	Bonhoeffer et al.	
2012/0310336	A1	12/2012	Figulla et al.	
2013/0073035	A1	3/2013	Tuval et al.	
2013/0079869	A1	3/2013	Straubinger et al.	

FOREIGN PATENT DOCUMENTS

DE	19546692	6/1997
DE	19857887	7/2000
DE	19907646	8/2000
DE	10010074	10/2001
DE	10049812	4/2002
DE	10049813	4/2002
DE	10049814	4/2002
DE	10049815	4/2002
DE	102006052564	12/2007
EP	0103546	3/1984
EP	0144167	6/1985
EP	0597967	12/1994
EP	0592410	10/1995
EP	0850607	7/1998
EP	1057460	12/2000
EP	1088529	4/2001
EP	1469797	10/2004

(56) **References Cited**

FOREIGN PATENT DOCUMENTS

EP	1570809	9/2005
EP	1653888	5/2006
FR	2815844	5/2002
FR	2788217	7/2007
GB	2056023	3/1981
SU	1271508	11/1986
WO	WO 91/17720	11/1991
WO	WO 92/17118	10/1992
WO	WO 93/01768	2/1993
WO	WO 97/24080	7/1997
WO	WO 98/29057	7/1998
WO	WO 99/33414	7/1999
WO	WO 99/40964	8/1999
WO	WO 99/47075	9/1999
WO	WO 00/18333	4/2000
WO	WO 00/41652	7/2000
WO	WO 00/47139	8/2000
WO	WO 01/28459	4/2001
WO	WO 01/35878	5/2001
WO	WO 01/49213	7/2001
WO	WO 01/54624	8/2001
WO	WO 01/54625	8/2001
WO	WO 01/62189	8/2001
WO	WO 01/64137	9/2001
WO	WO 01/76510	10/2001
WO	WO 02/22054	3/2002
WO	WO 02/36048	5/2002
WO	WO 02/41789	5/2002
WO	WO 02/43620	6/2002
WO	WO 02/47575	6/2002
WO	WO 02/49540	6/2002
WO	WO 03/047468	6/2003
WO	WO 2005/034812	4/2005
WO	WO 2005/087140	9/2005
WO	WO 2005/102015	11/2005
WO	WO 2006/014233	2/2006
WO	WO 2006/034008	3/2006
WO	WO 2006/108090	10/2006
WO	WO 2006/111391	10/2006
WO	WO 2006/138173	12/2006
WO	WO 2008/005405	1/2008
WO	WO 2008/035337	3/2008
WO	WO 2008/147964	12/2008
WO	WO 2008/150529	12/2008
WO	WO 2009/024859	2/2009
WO	2009053952 A2	4/2009
WO	WO 2009/116041	9/2009
WO	2011034628 A1	3/2011
WO	2013059747 A1	4/2013

OTHER PUBLICATIONS

Almagor, M.D., Yaron, et al., "Balloon Expandable Stent Implantation in Stenotic Right Heart Valved Conduits," Journal of the American College of Cardiology, vol. 16, No. 6, pp. 1310-1314, Nov. 1, 1990; ISSN 0735-1097.

Al Zaibag, Muayed, et al., "Percutaneous Balloon Valvotomy in Tricuspid Stenosis," British Heart Journal, Jan. 1987, vol. 57, No. 1, pp. 51-53.

Andersen, et al., "Transluminal implantation of artificial heart valves. Description of a new expandable aortic valve and initial results with implantation by catheter technique in closed chest pigs." European Heart Journal (1992), 13, 704-708.

Andersen, Henning Rud, "History of Percutaneous Aortic Valve Prosthesis," Herz 34 2009 Nr. 5, Urban & Vogel, pp. 343-346, Skejby University Hospital Department of Cardiology, Aarhus, Denmark.

Benchimol, Alberto, et al., "Simultaneous Left Ventricular Echocardiography and Aortic Blood Velocity During Rapid Right Ventricular Pacing in Man," The American Journal of the Medical Sciences, Jan.-Feb. 1977 vol. 273, No. 1, pp. 55-62.

Dake, Transluminal Placement of Endovascular Stent-Grafts for the Treatment of Descending Thoracic Aortic Aneurysms, New Engl.J. Med., 1994; 331:1729-34.

Dotter, M.D., Charles T., "Transluminal Treatment of Arteriosclerotic Obstruction," University of Oregon's Minthorn Memorial Laboratory for Cardiovascular Research through Radiology, Circulation, vol. XXX, Nov. 1964, pp. 654-670.

Kolata, Gina, "Device That Opens Clogged Arteries Gets a Failing Grade in a New Study," nytimes.com, http://www.nytimes.com/1991/01/03/health/device-that-opens-clogged-arteries-gets-a-faili . . . , Jul. 29, 2009, 2 pages.

Inoune, M.D., Kanji, et al., "Clinical Application of Transvenous Mitral Commissurotomy by a New Balloon Catheter," The Journal of Thoracic and Cardiovascular Surgery 87:394-402, 1984.

Lawrence, Jr., M.D., David D., "Percutaneous Endovascular Graft: Experimental Evaluation," Radiology 1897; 163: 357-360.

Pavcnik, M.D., Ph.D., Dusan, et al. "Development and Initial Experimental Evaluation of a Prosthetic Aortic Valve for Transcatheter Placement," Cardiovascular Radiology 1992; 183:151-154.

Porstmann, W., et al., "Der Verschluβ des Ductus Arteriosus Persistens ohne Thorakotomie," Thoraxchirurgie Vaskuläre Chirurgie, Band 15, Heft 2, Stuttgart, im Apr. 1967, pp. 199-203.

Rashkind, M.D., William J., "Creation of an Atrial Septal Defect Withoput Thoracotomy," The Journal of the American Medical Association, vol. 196, No. 11, Jun. 13, 1966, pp. 173-174.

Rashkind, M.D., William J., "Historical Aspects of Interventional Cardiology: Past, Present, Future," Texas Heart Institute Journal, Interventional Cardiology, pp. 363-367.

Rösch, M.D., Josef, "The Birth, Early Years and Future of Interventional Radiology," J Vasc Interv Radiol 2003; 14:841-853.

Ross, F.R.C.S., D.N., "Aortic Valve Surgery," Guy's Hospital, London, pp. 192-197, approximately 1968.

Sabbah, Ph.D., Hani N., et al., "Mechanical Factors in the Degeneration of Porcine Bioprosthetic Valves: An Overview," Journal of Cardiac Surgery, vol. 4, No. 4, pp. 302-309, Dec. 1989; ISSN 0886-0440.

Selby, M.D., J. Bayne, "Experience with New Retrieval Forceps for Foreign Body Removal in the Vascular, Urinary, and Biliary Systems," Radiology 1990; 176:535-538.

Serruys, P.W., et al., "Stenting of Coronary Arteries. Are we the Sorcerer's Apprentice?," European Heart Journal (1989) 10, 774-782, pp. 37-45, Jun. 13, 1989.

Sigwart, Ulrich, "An Overview of Intravascular Stents: Old and New," Chapter 48, Textbook of Interventional Cardiology, 2nd Edition, W.B. Saunders Company, Philadelphia, PA, © 1994, 1990, pp. 803-815.

Uchida, Barry T., et al., "Modifications of Gianturco Expandable Wire Stents," AJR:150, May 1988, Dec. 3, 1987, pp. 1185-1187.

Urban, M.D., Philip, "Coronary Artery Stenting," Editions Médecine et Hygiéne, Genéve, 1991, pp. 5-47.

Watt, A.H., et al. "Intravenous Adenosine in the Treatment of Supraventricular Tachycardia; a Dose-Ranging Study and Interaction with Dipyridamole," British Journal of Clinical Pharmacology (1986), 21, 227-230.

Wheatley, M.D., David J., "Valve Prostheses," Rob & Smith's Operative Surgery, Fourth Edition, pp, 415-424, Butterworths 1986.

CN Office Action issued in Application No. 201380057757.8, Issued Dec. 2, 2015.

Supplementary Search Report for European Application No. 13834484, dated Apr. 29, 2016.

* cited by examiner

Fig. 1

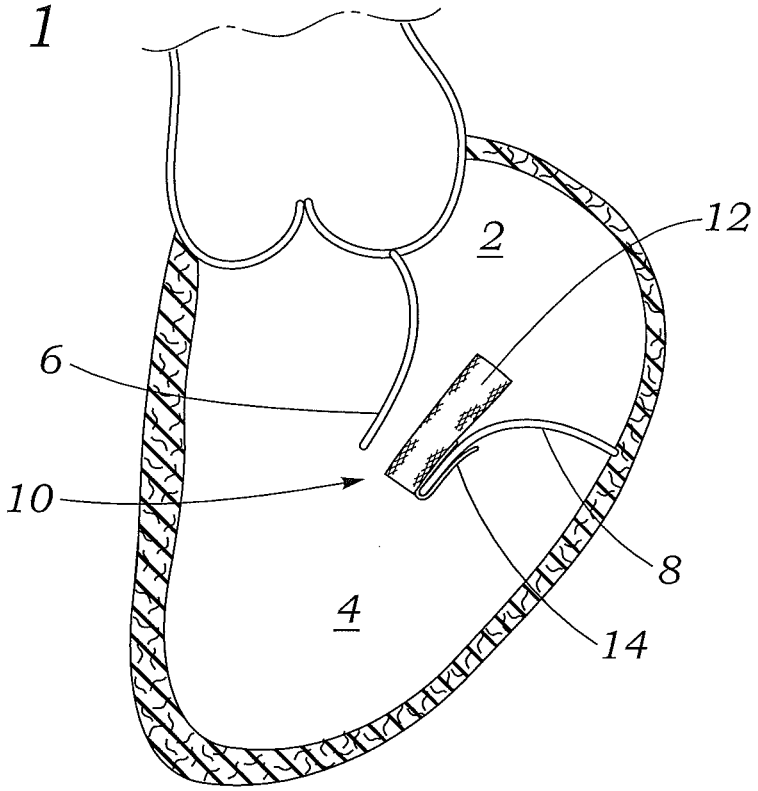


Fig. 2

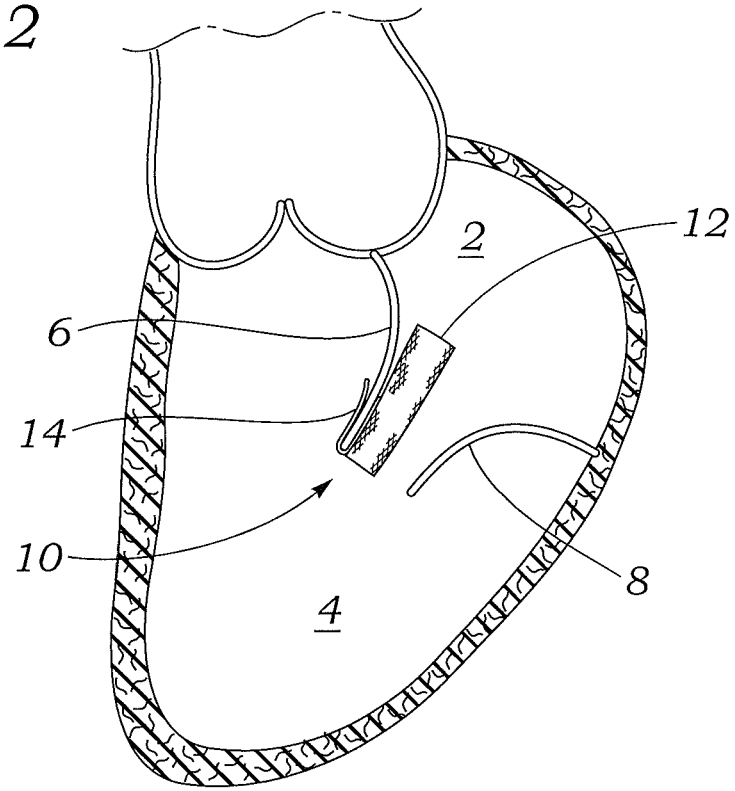


Fig. 3

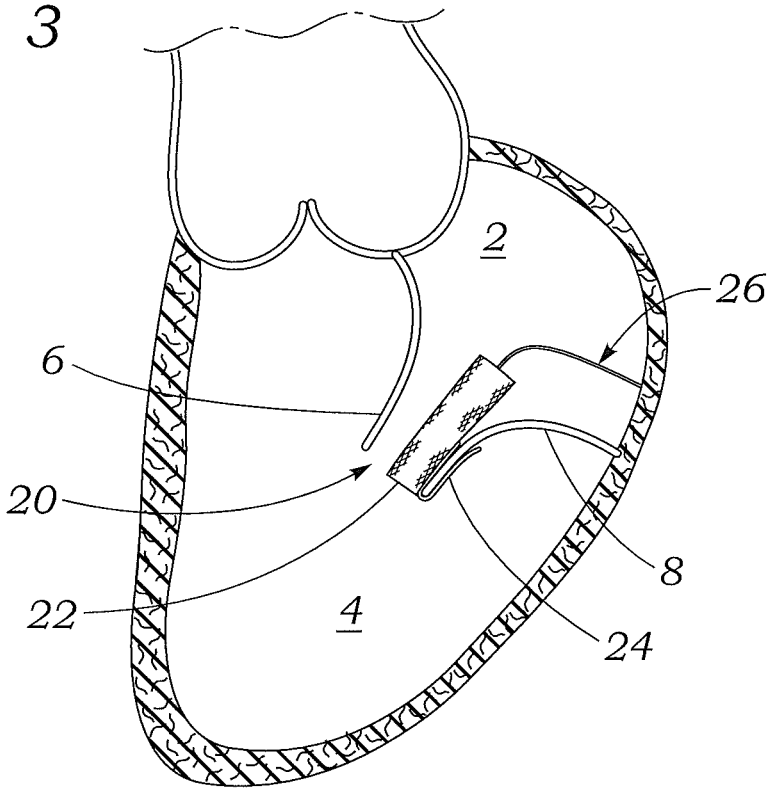


Fig. 4

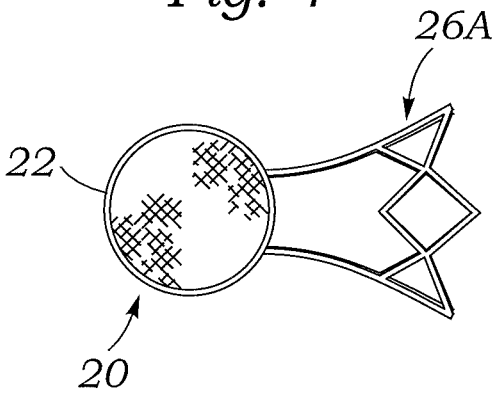


Fig. 5

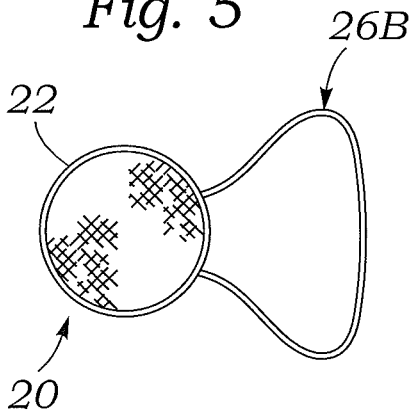


Fig. 6

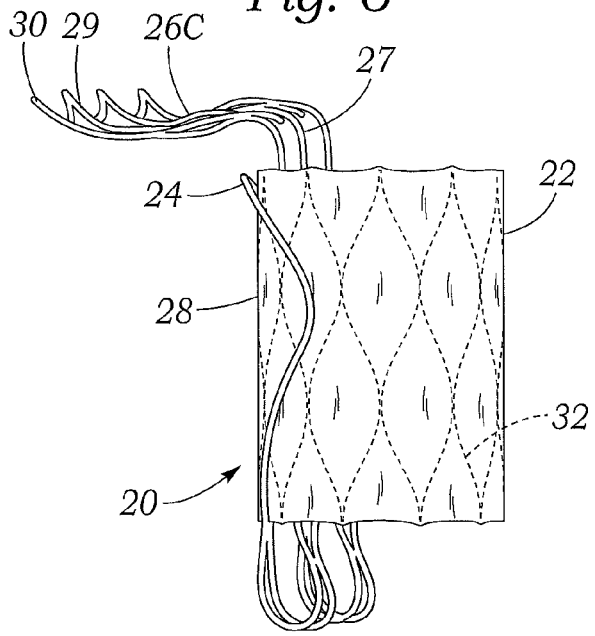


Fig. 7

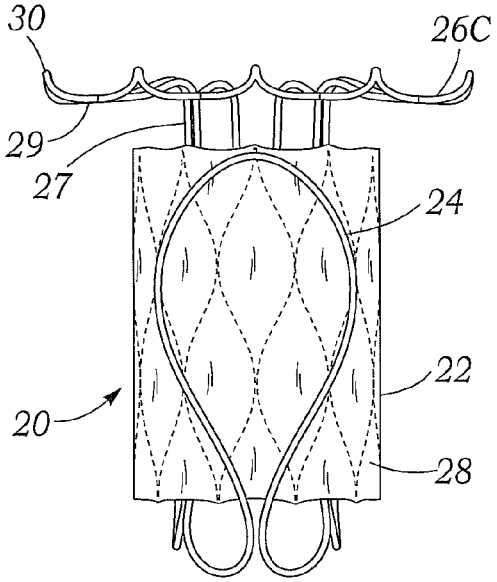


Fig. 8

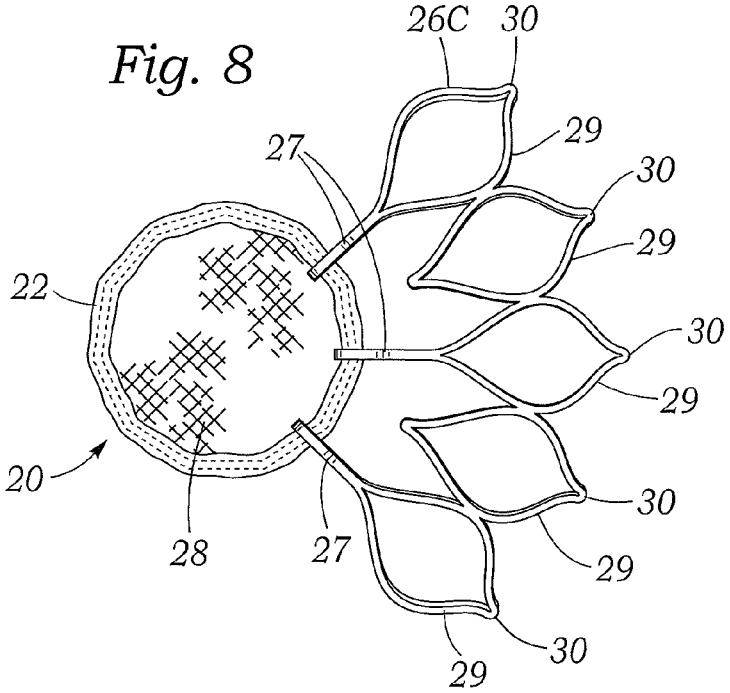


Fig. 9

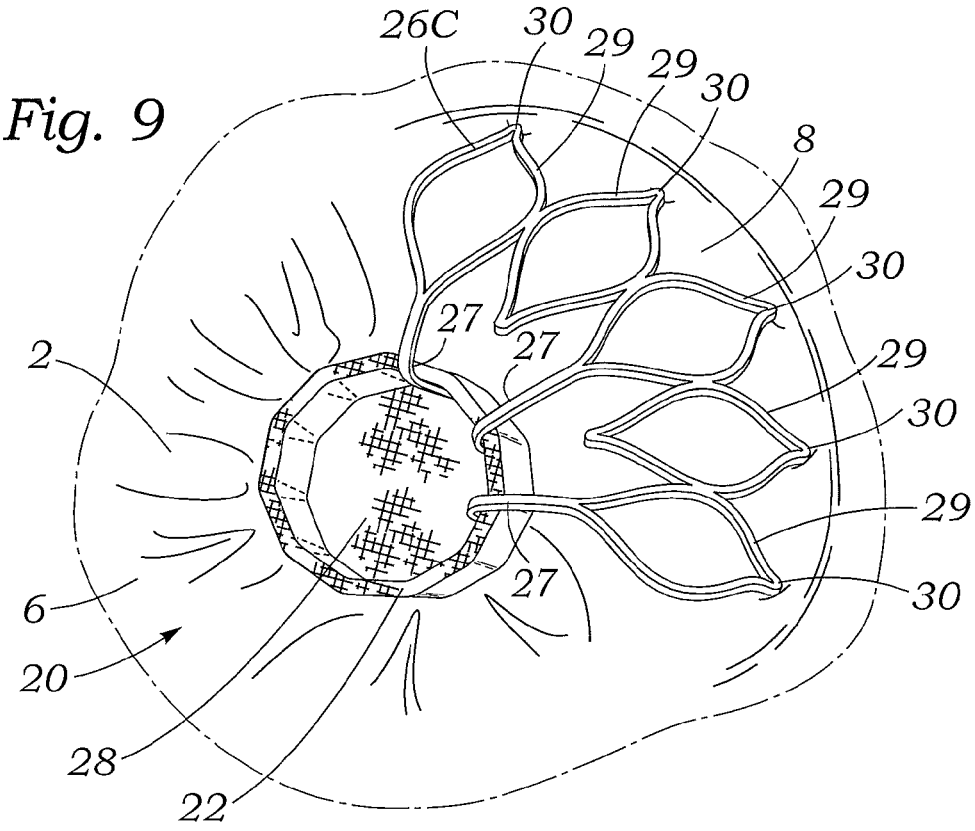

26C
30
29
29
30
8
29
30
27
27
2
29
30
29
27
30
6
20
28
22

Fig. 10

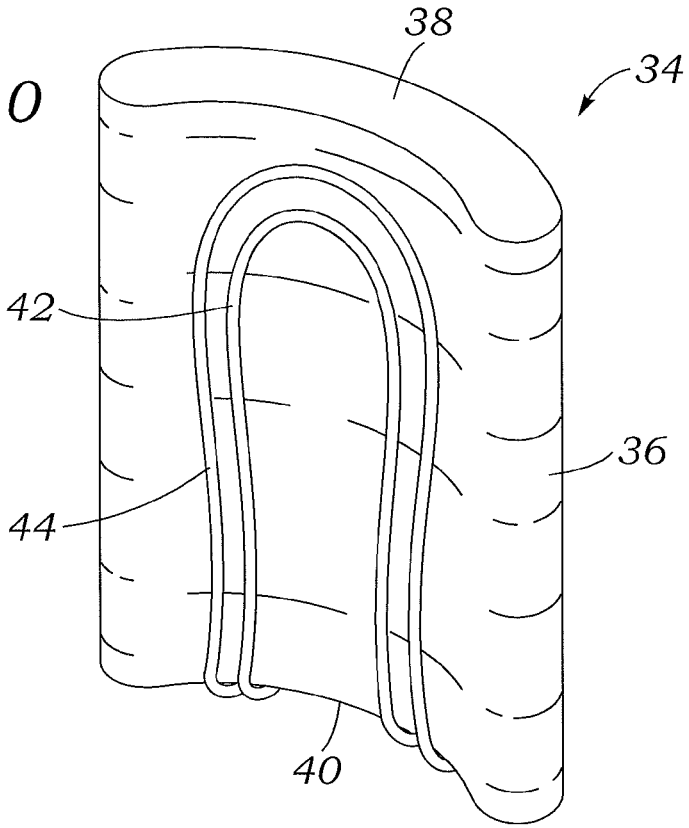

38
34
42
36
44
40

Fig. 11

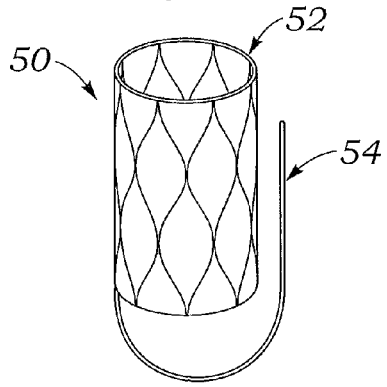


Fig. 12 Fig. 13 Fig. 14 Fig. 15

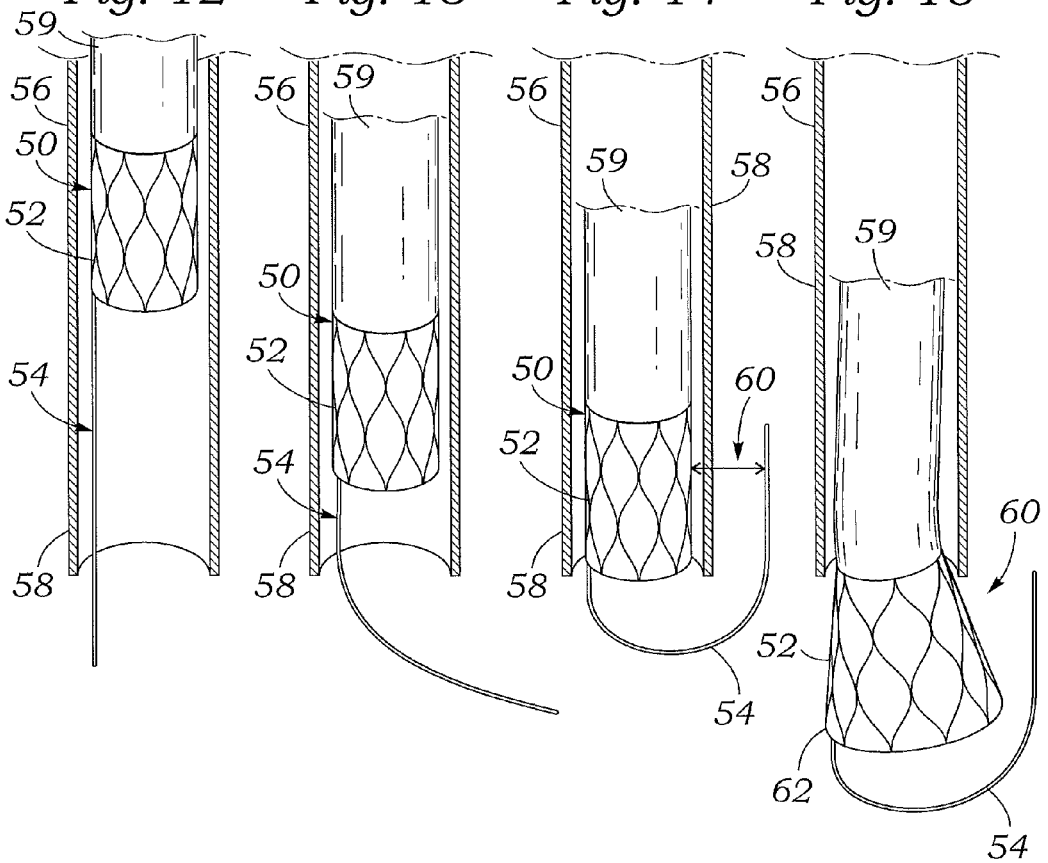


Fig. 16

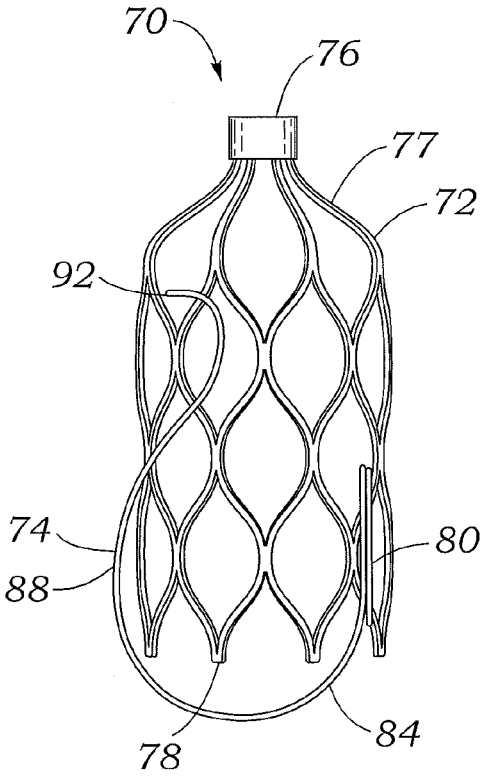


Fig. 17

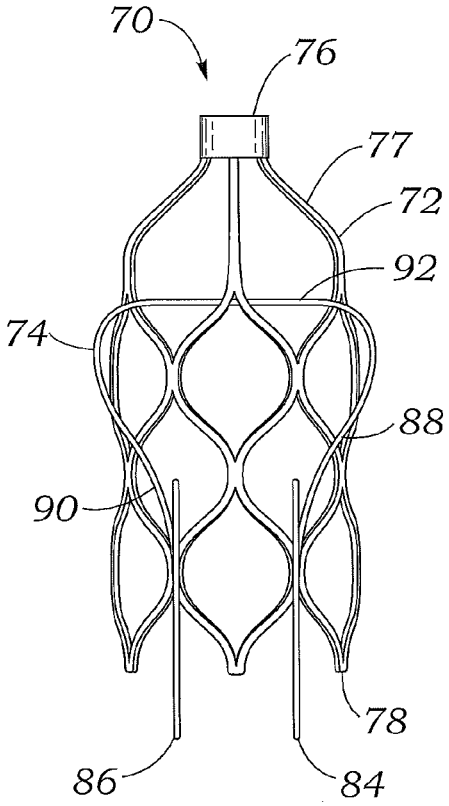


Fig. 18

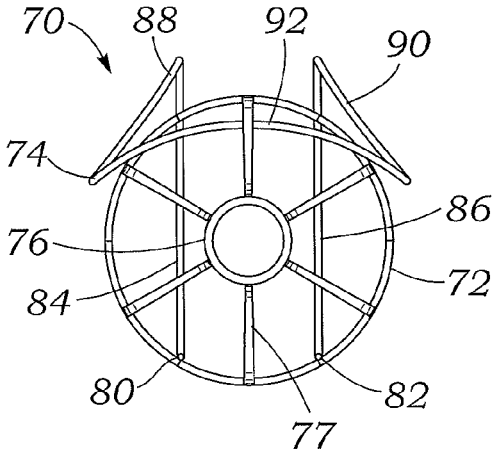


Fig. 19

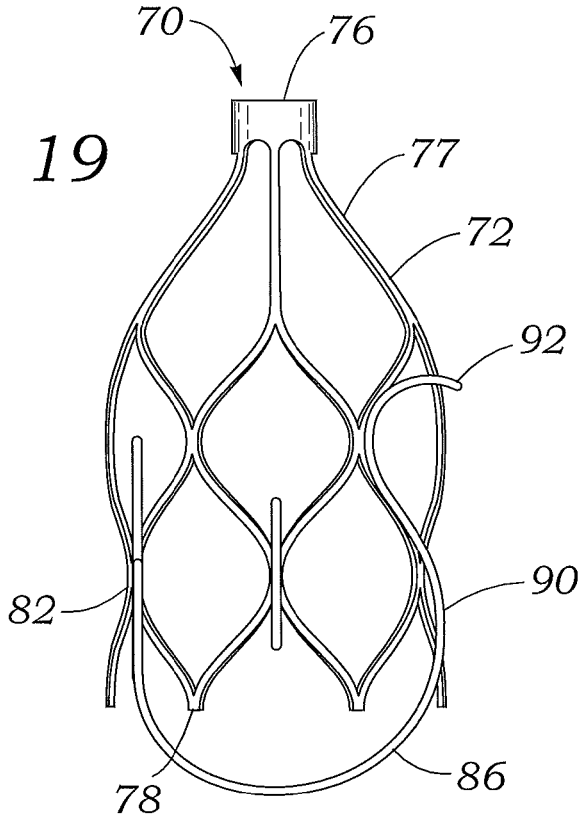


Fig. 20

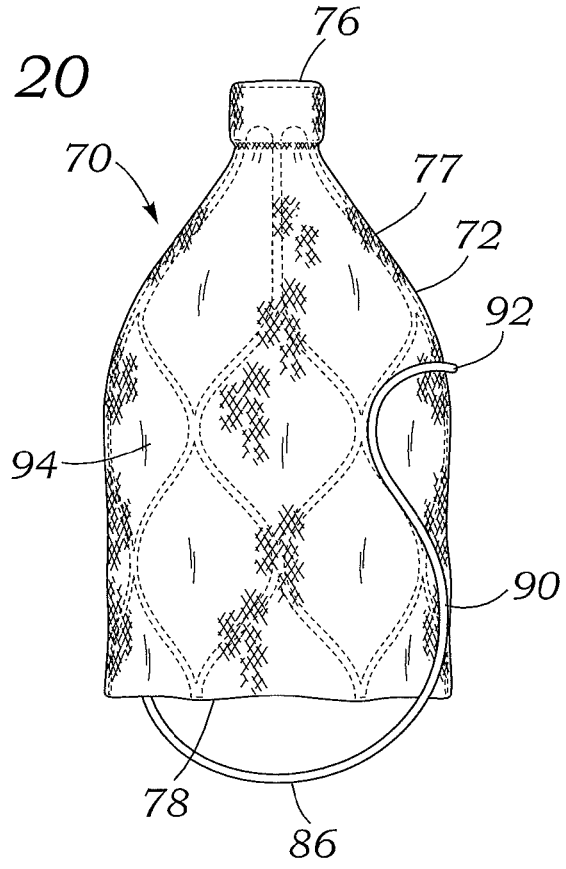


Fig. 21

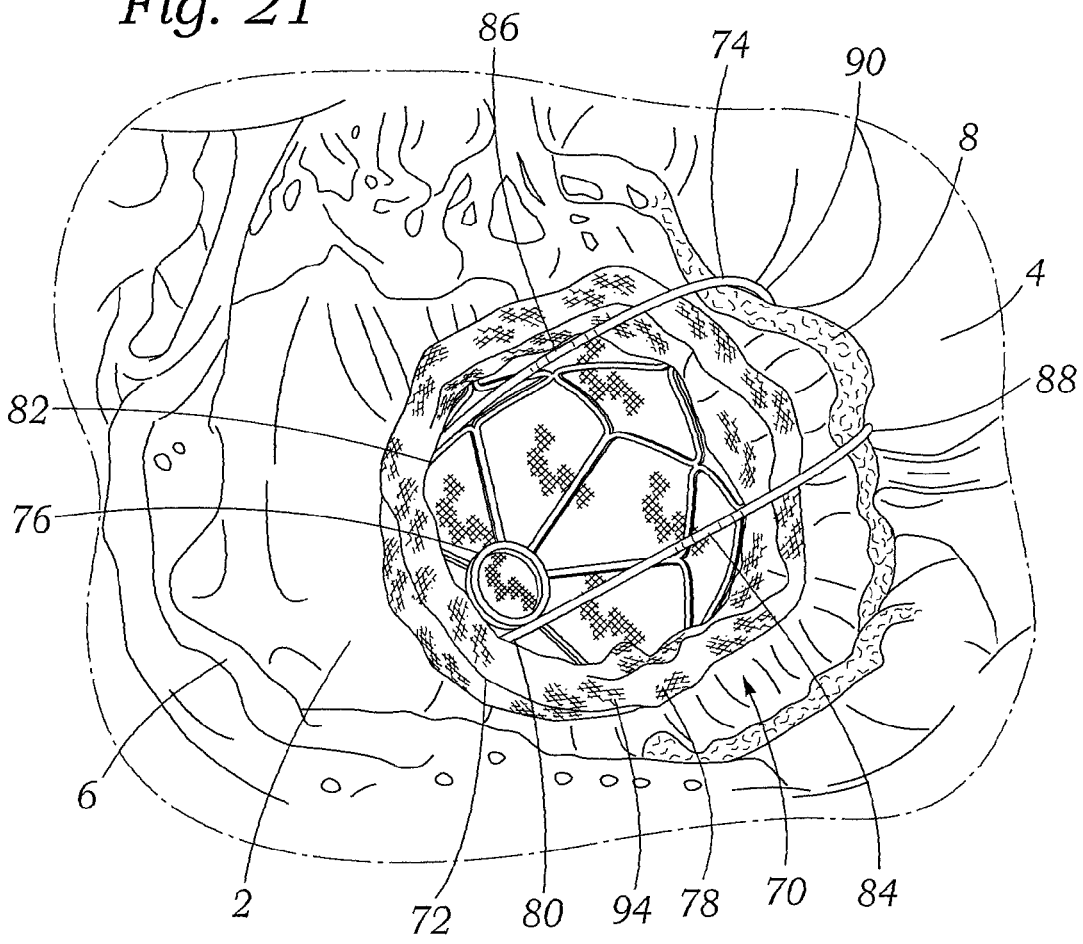

86
74
90
8
4
88
82
76
6
2
72
80
94
78
70
84

Fig. 24

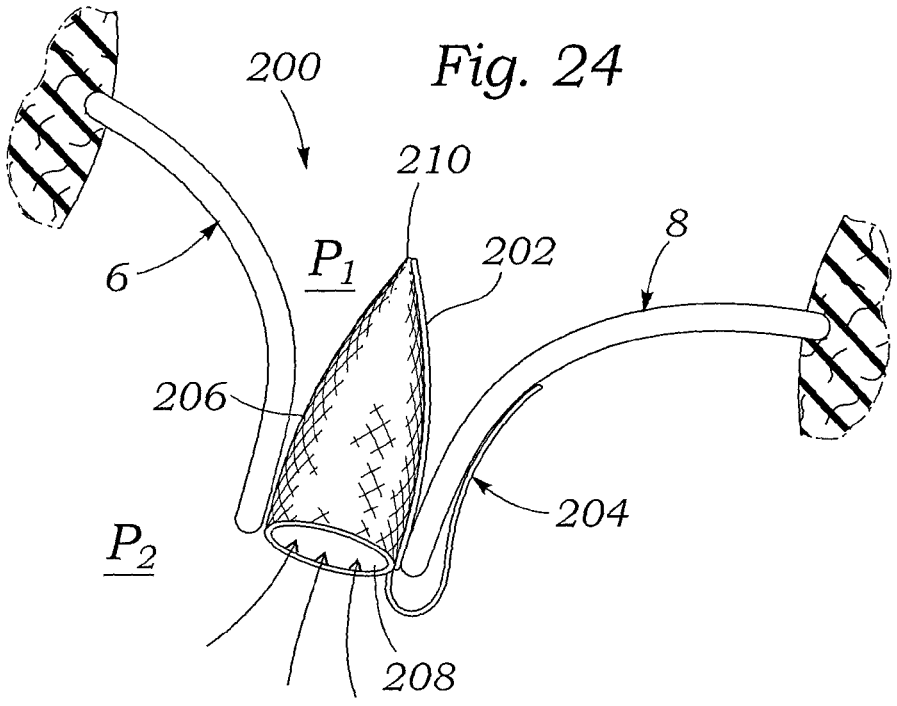

200
210
6
P1
202
8
206
204
P2
208

Fig. 22

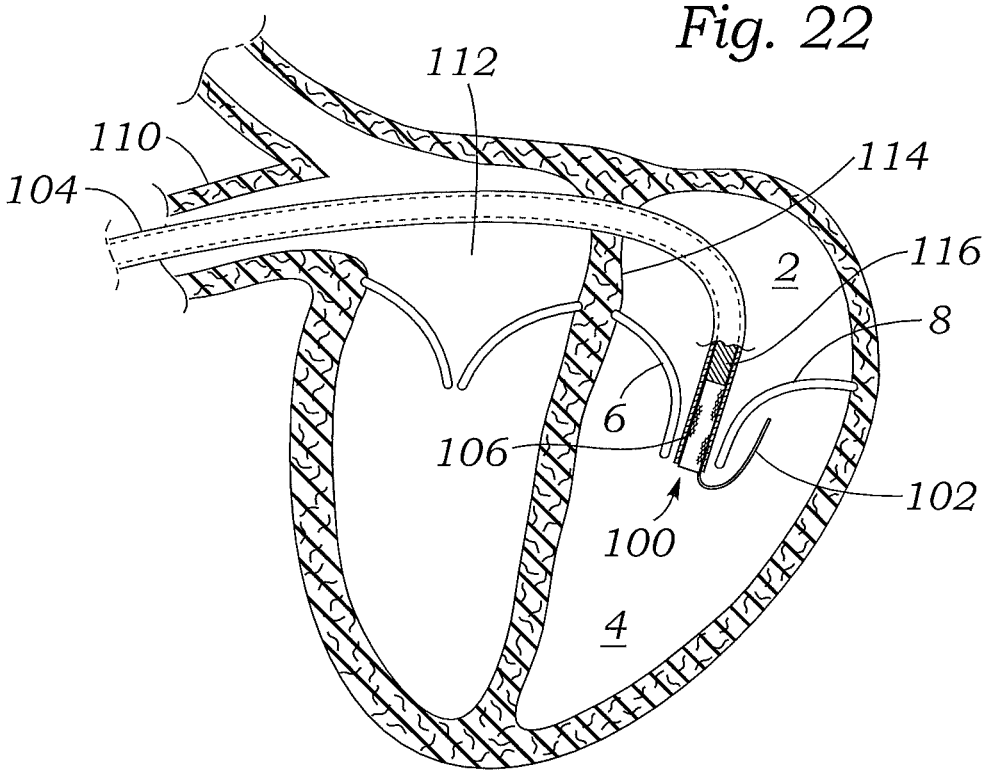


Fig. 23

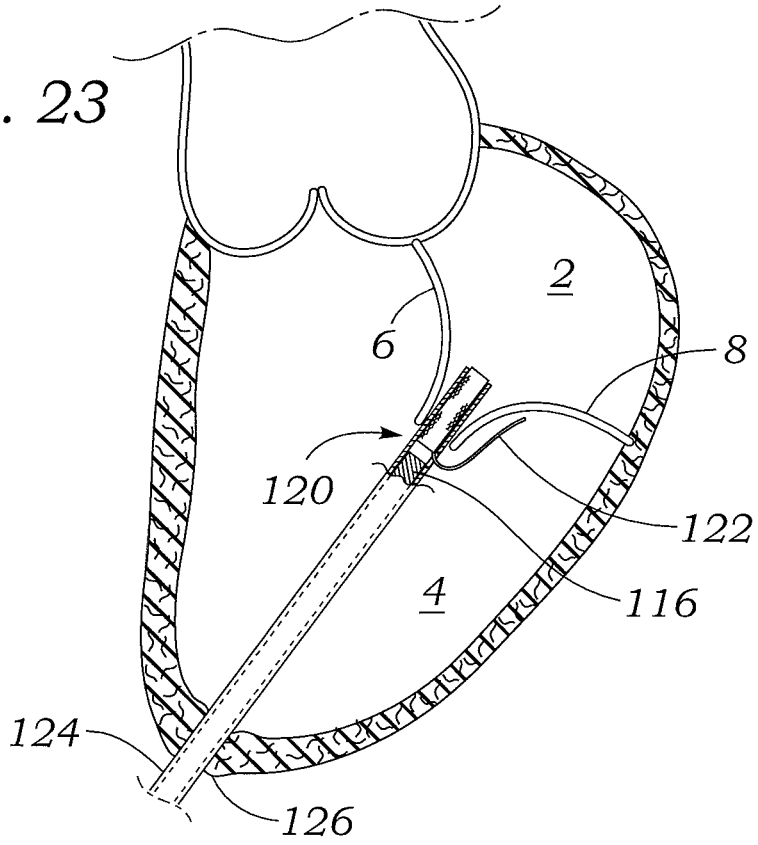


Fig. 25

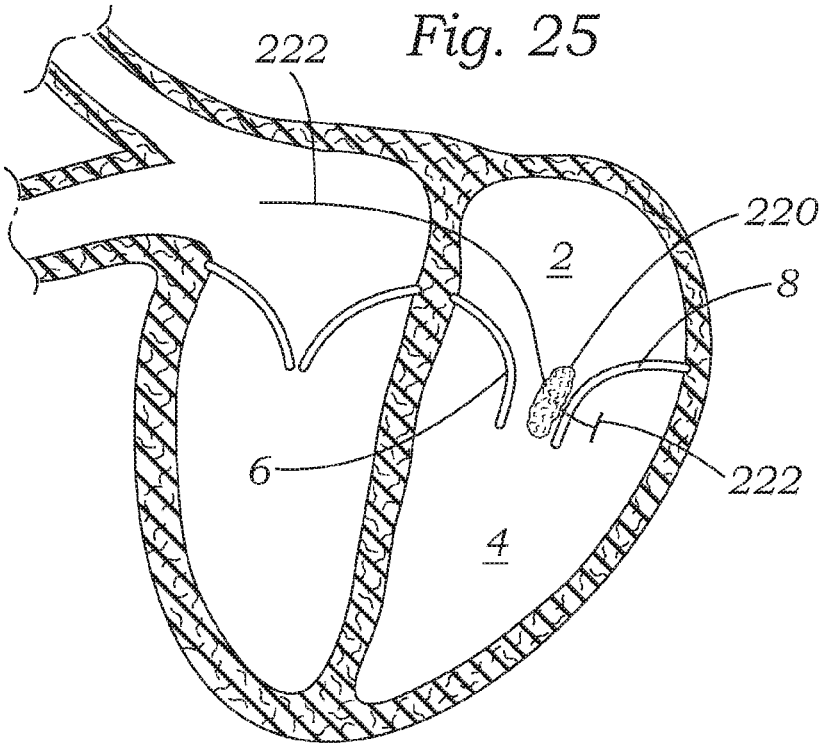


Fig. 26

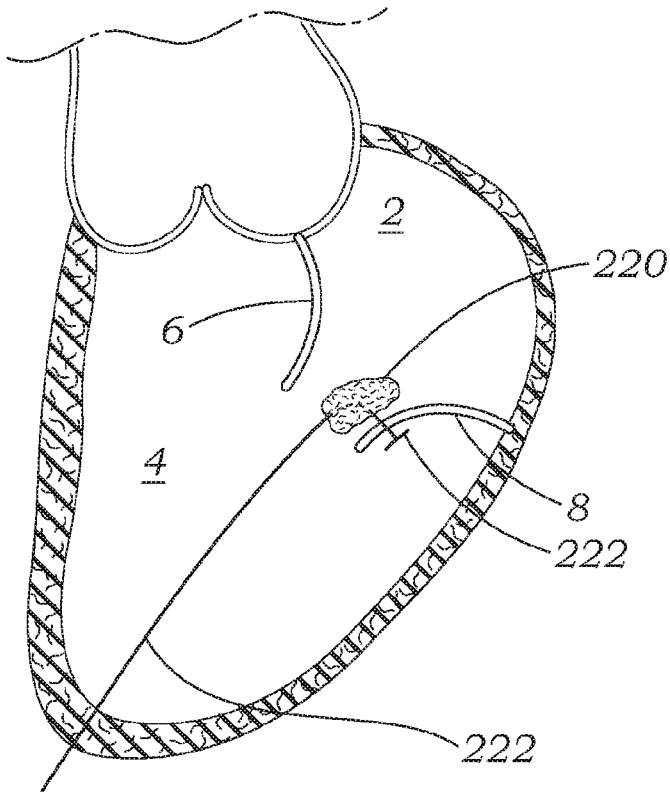


Fig. 27

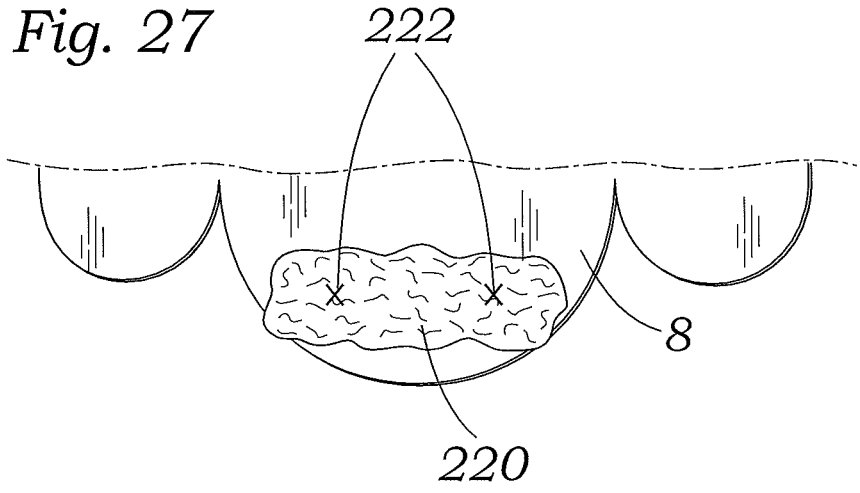


Fig. 28

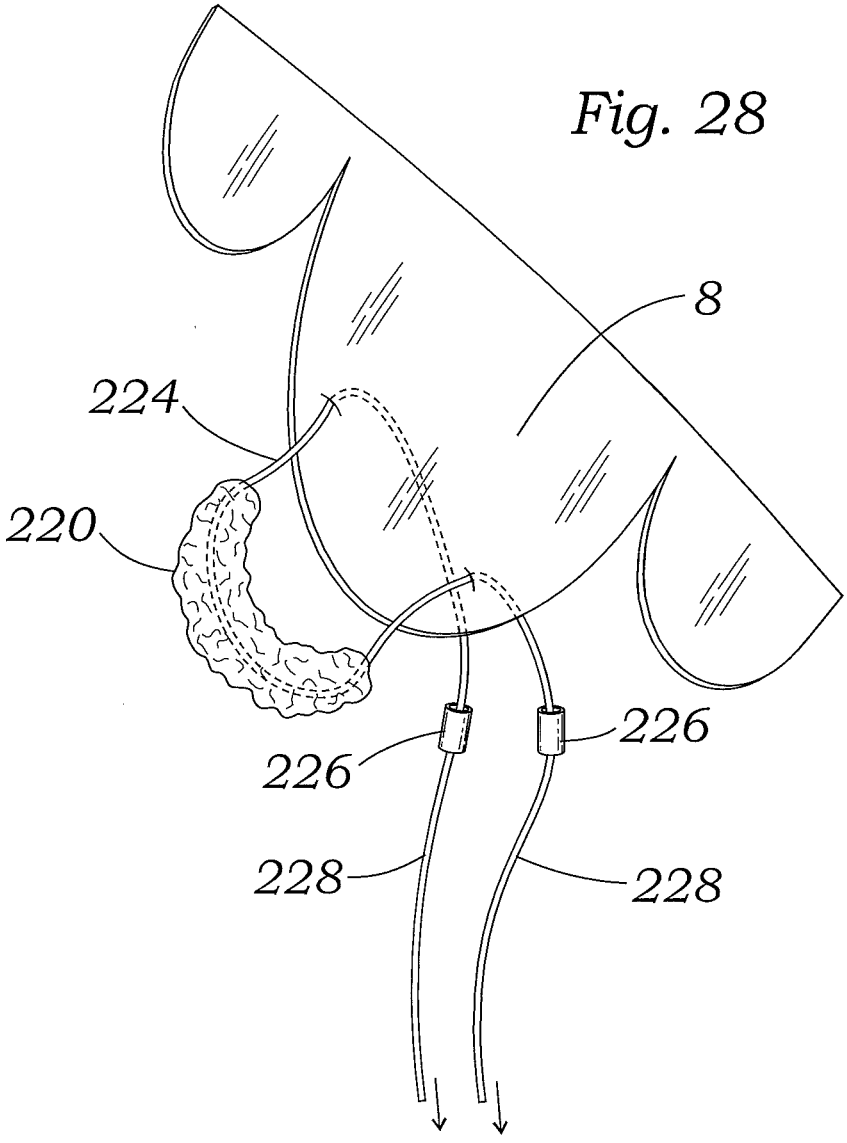


Fig. 29

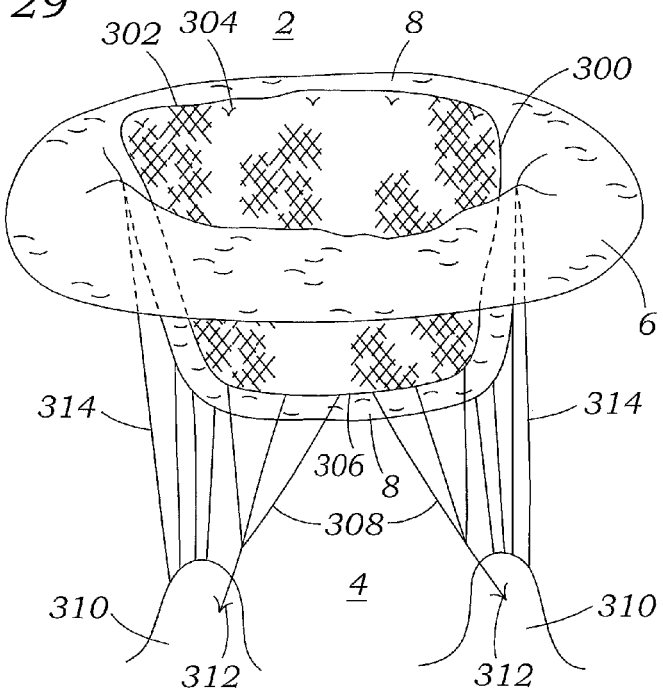


Fig. 30

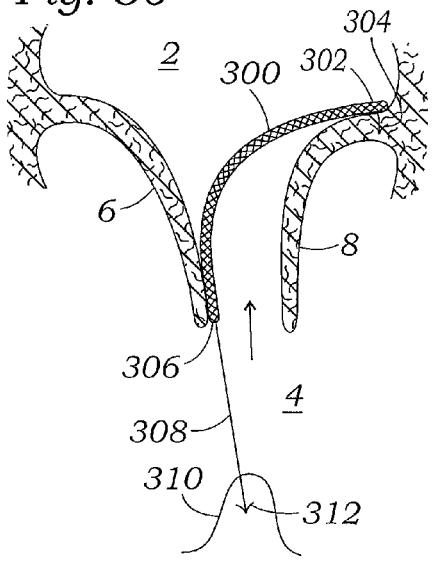


Fig. 31

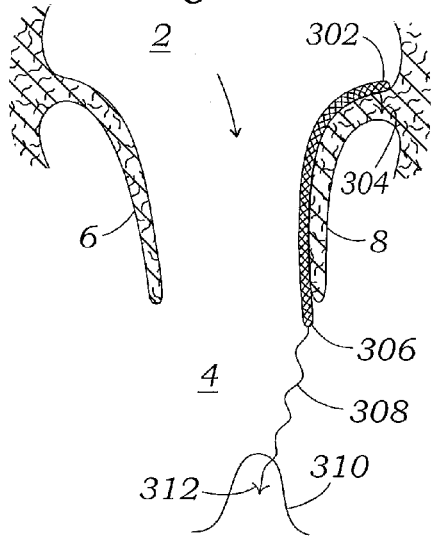


Fig. 32

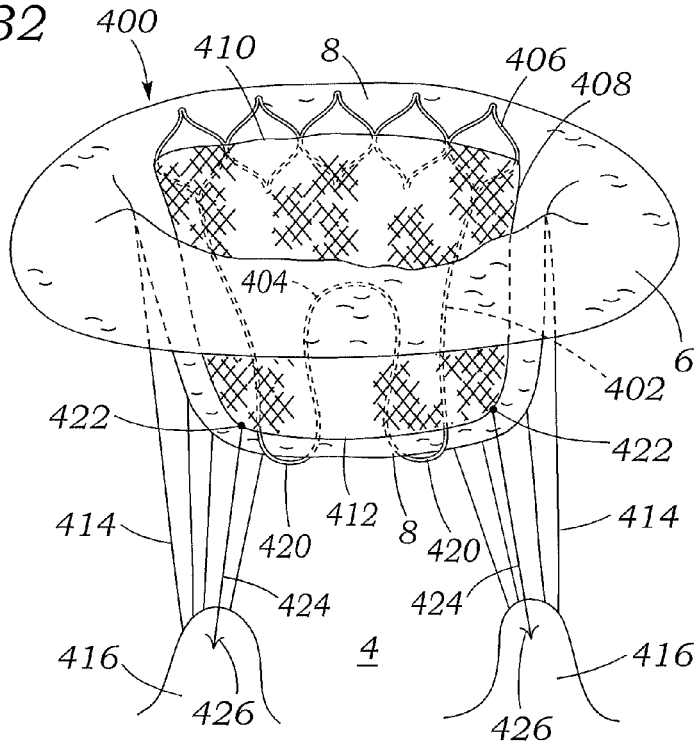


Fig. 33

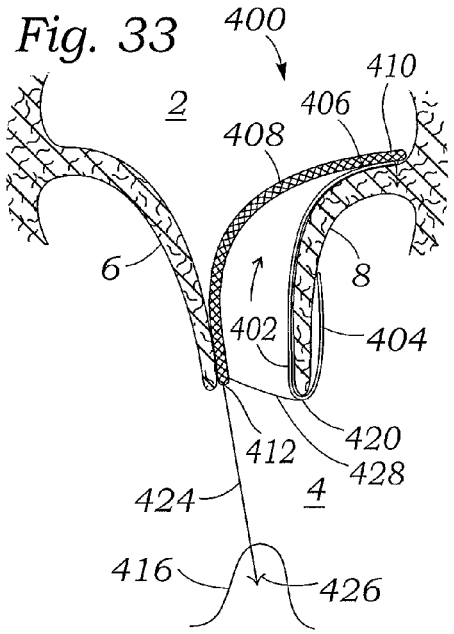


Fig. 34

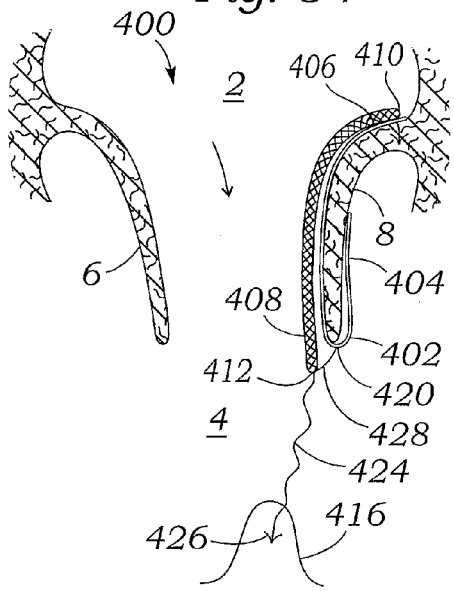


Fig. 36

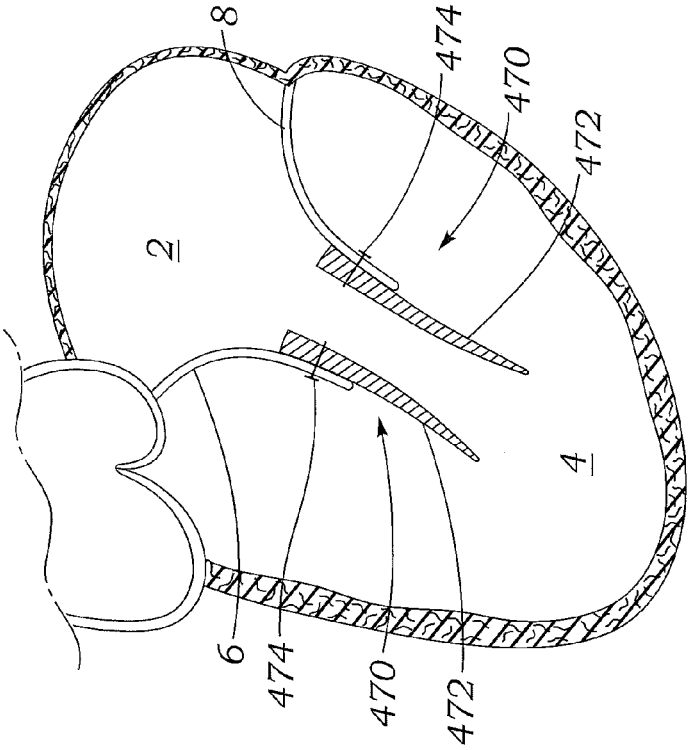
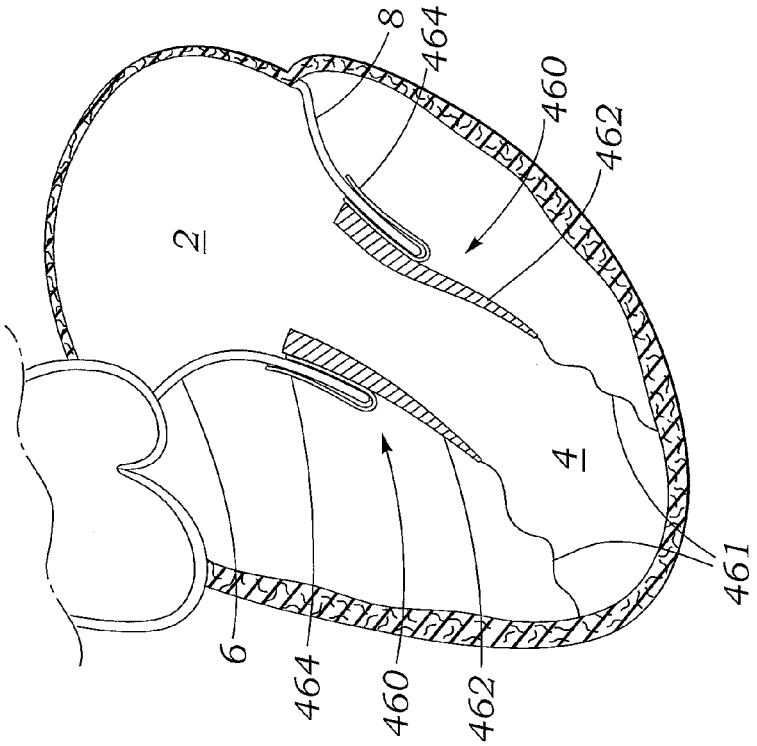


Fig. 35



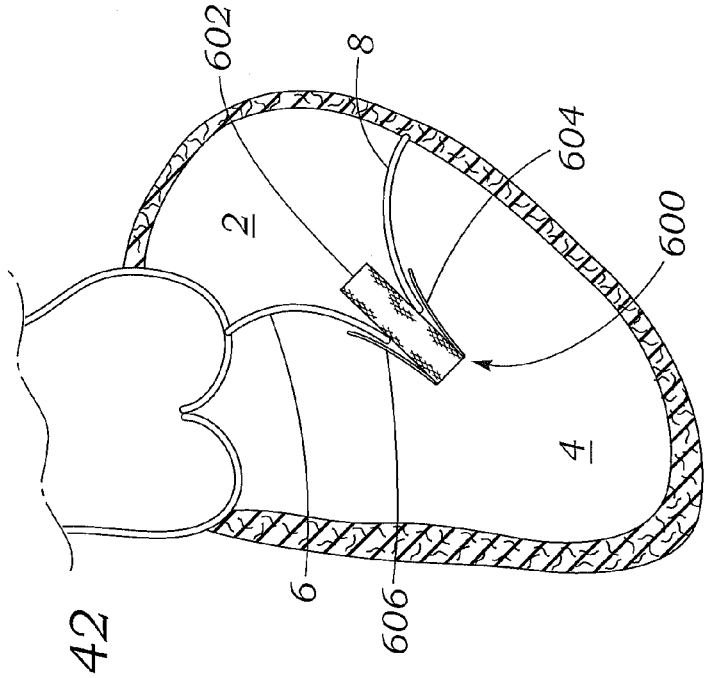

602
8
604
600
2
4
6
606

Fig. 42

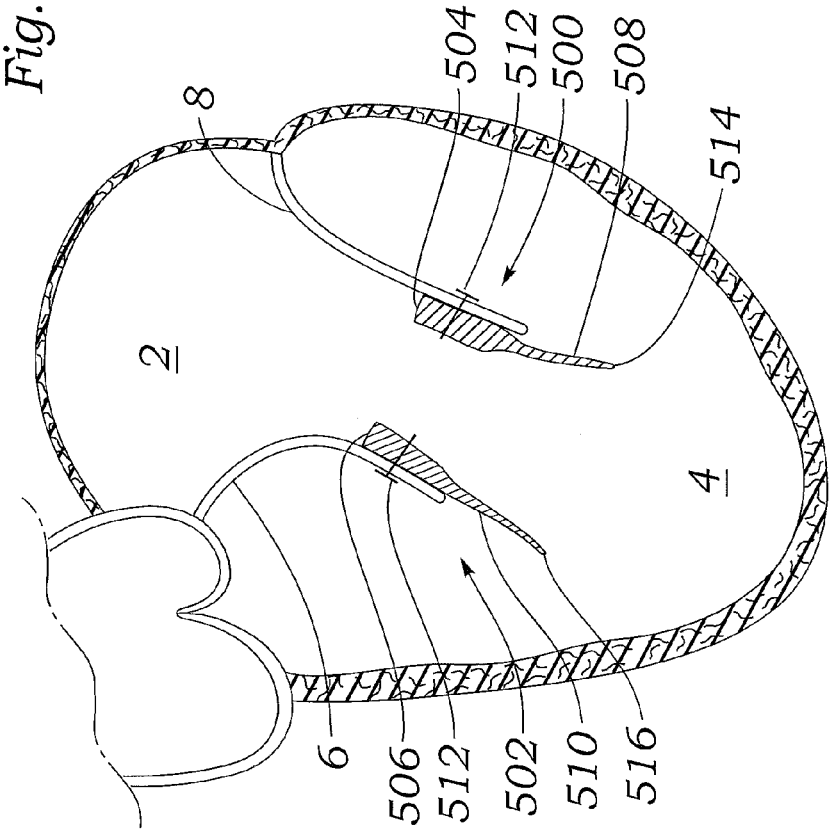

504
512
500
508
514
8
2
4
6
506
512
502
510
516

Fig. 37

Fig. 38

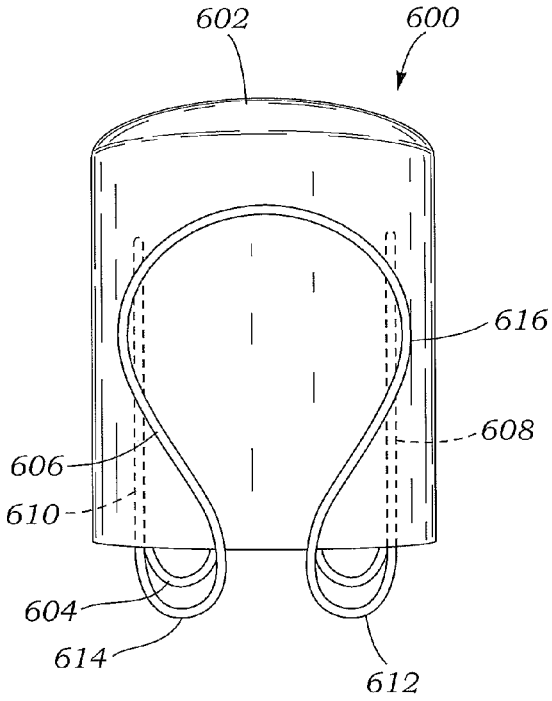


Fig. 39

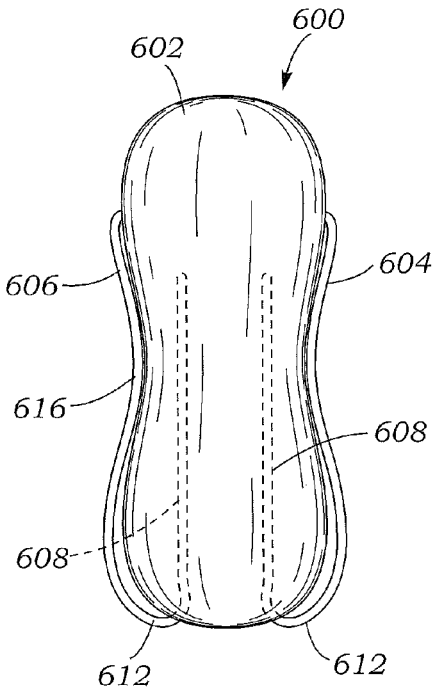


Fig. 40

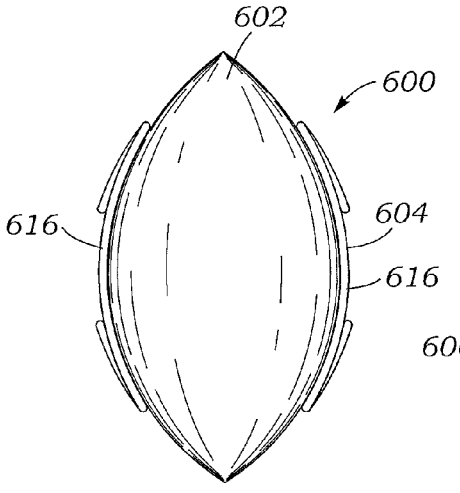


Fig. 41

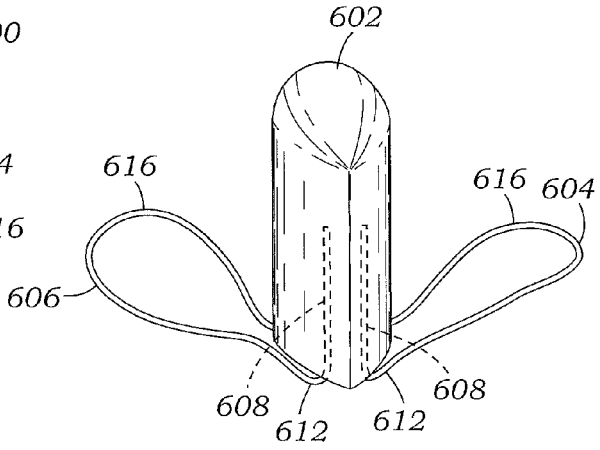


Fig. 43

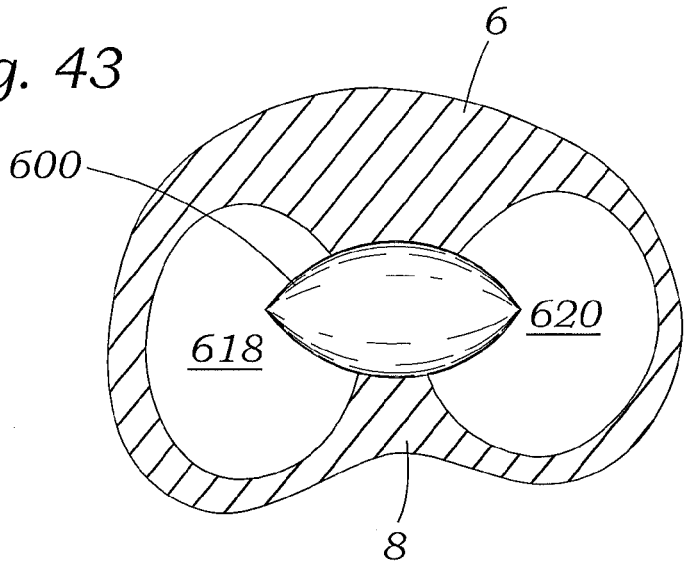


Fig. 44

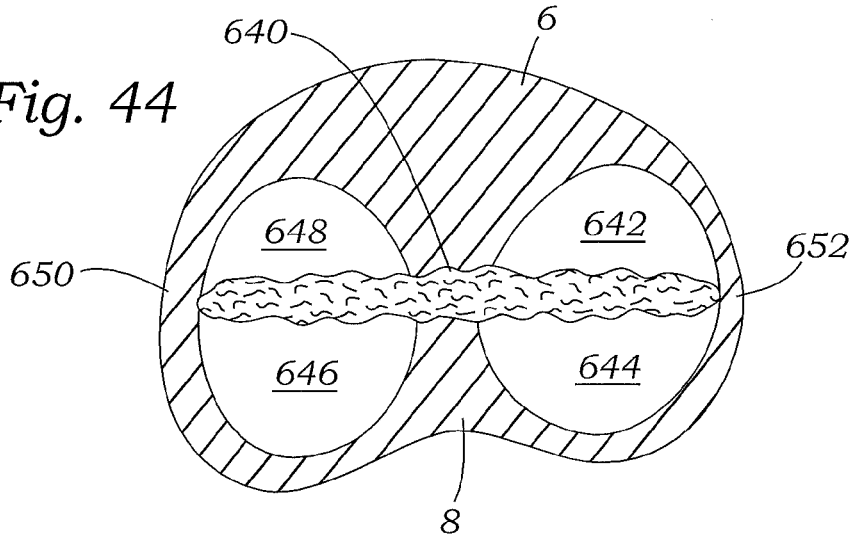


Fig. 45

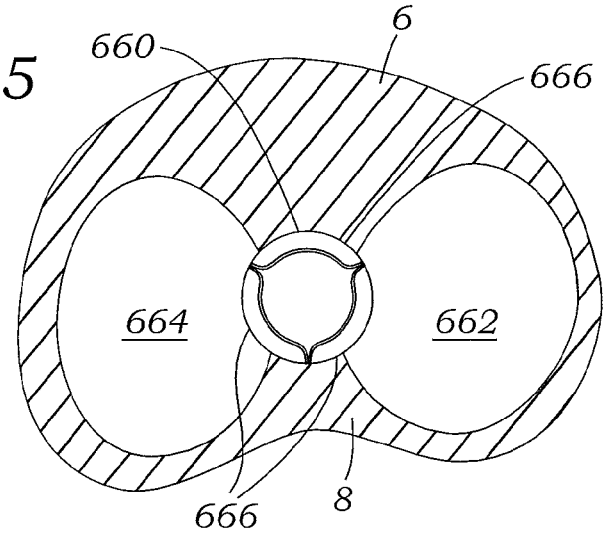


Fig. 46

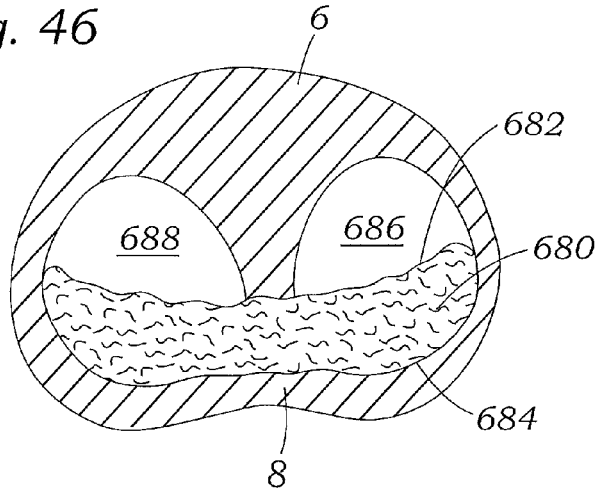


Fig. 47

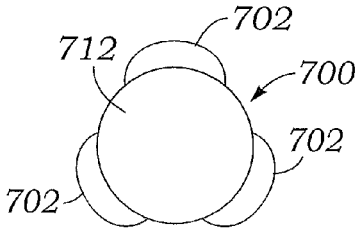


Fig. 48

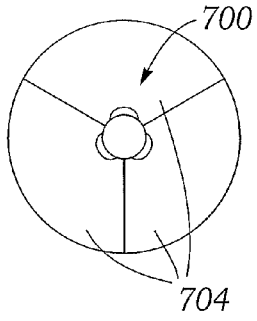


Fig. 49

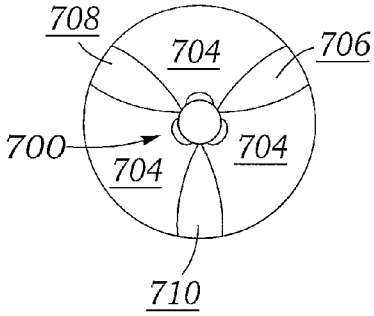


Fig. 50

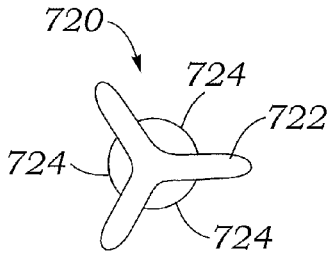


Fig. 51

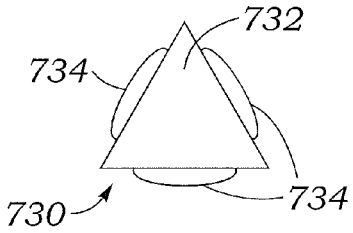


Fig. 52

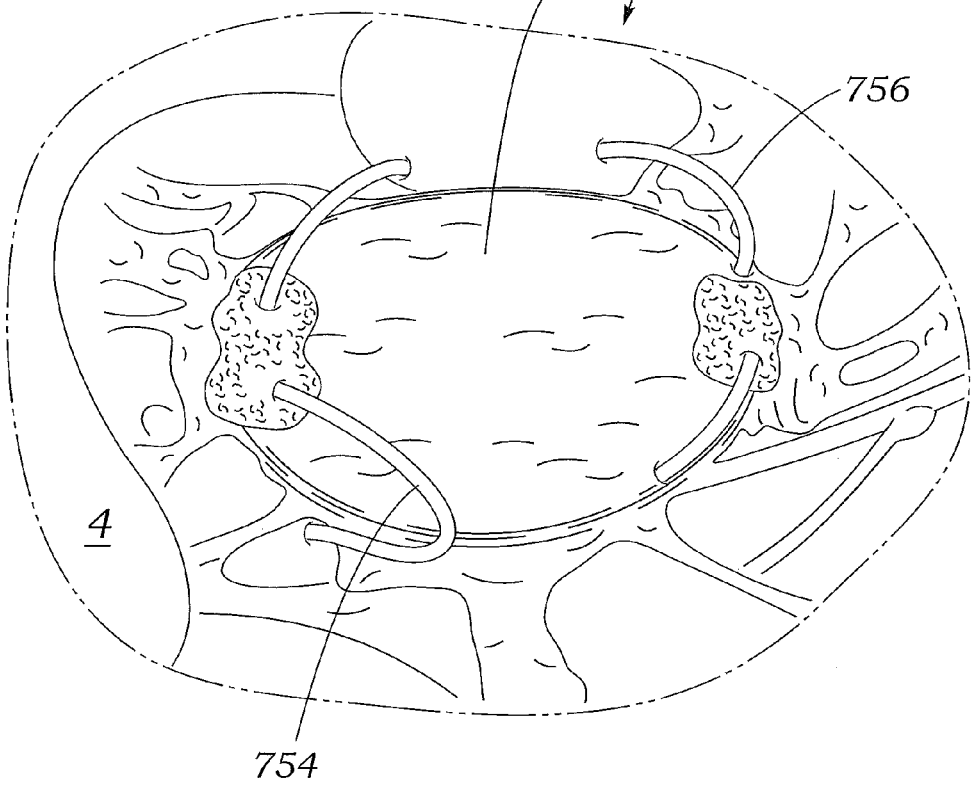


Fig. 53

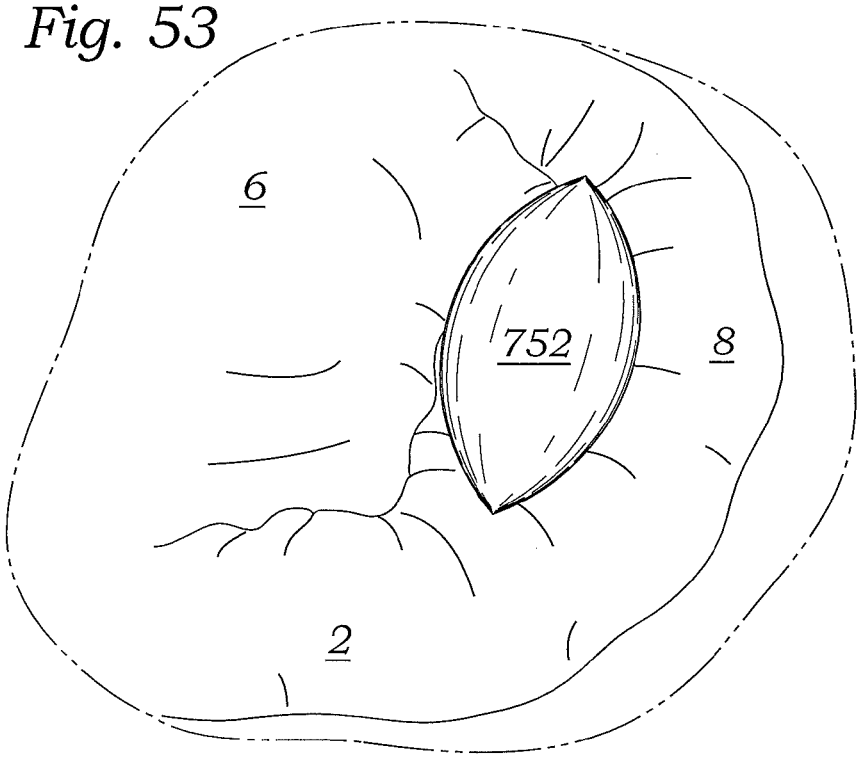
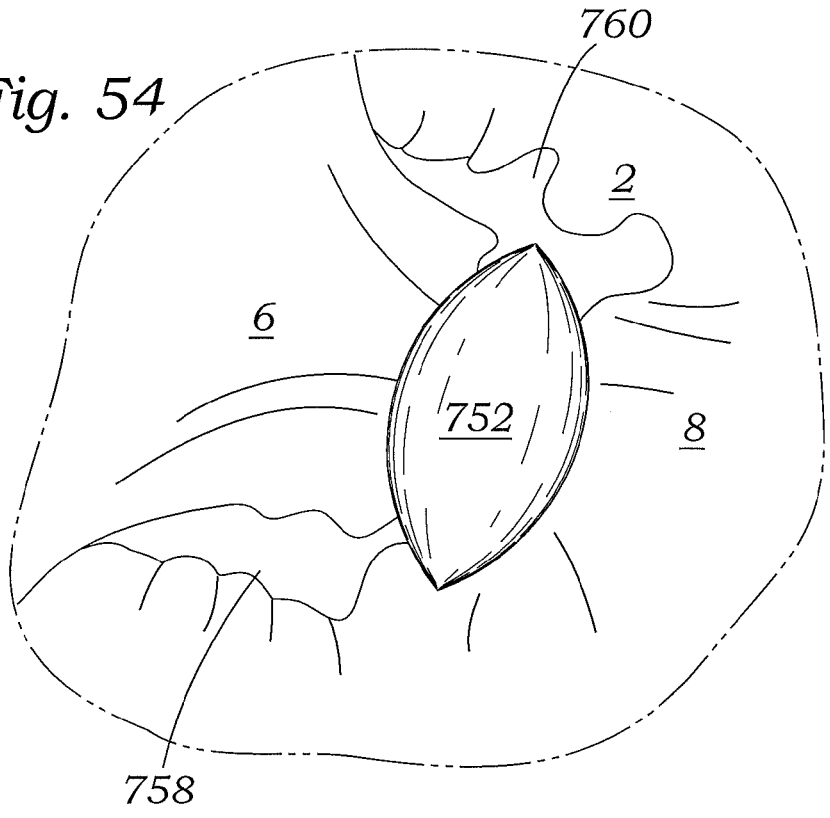


Fig. 54



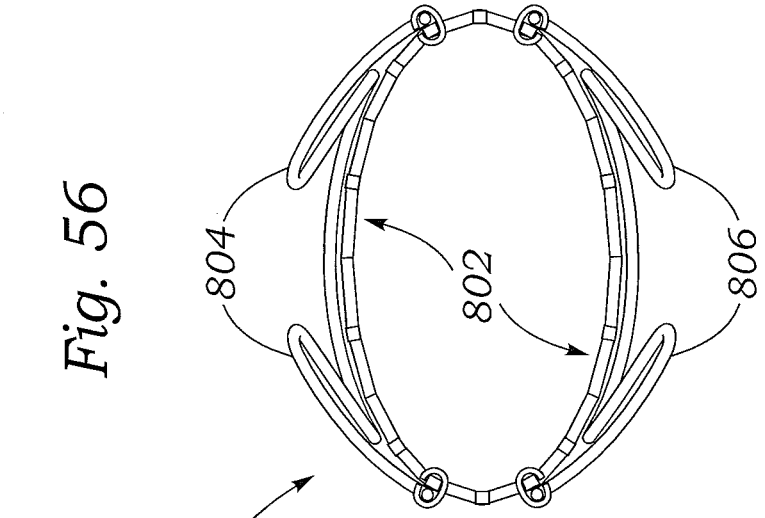


Fig. 56

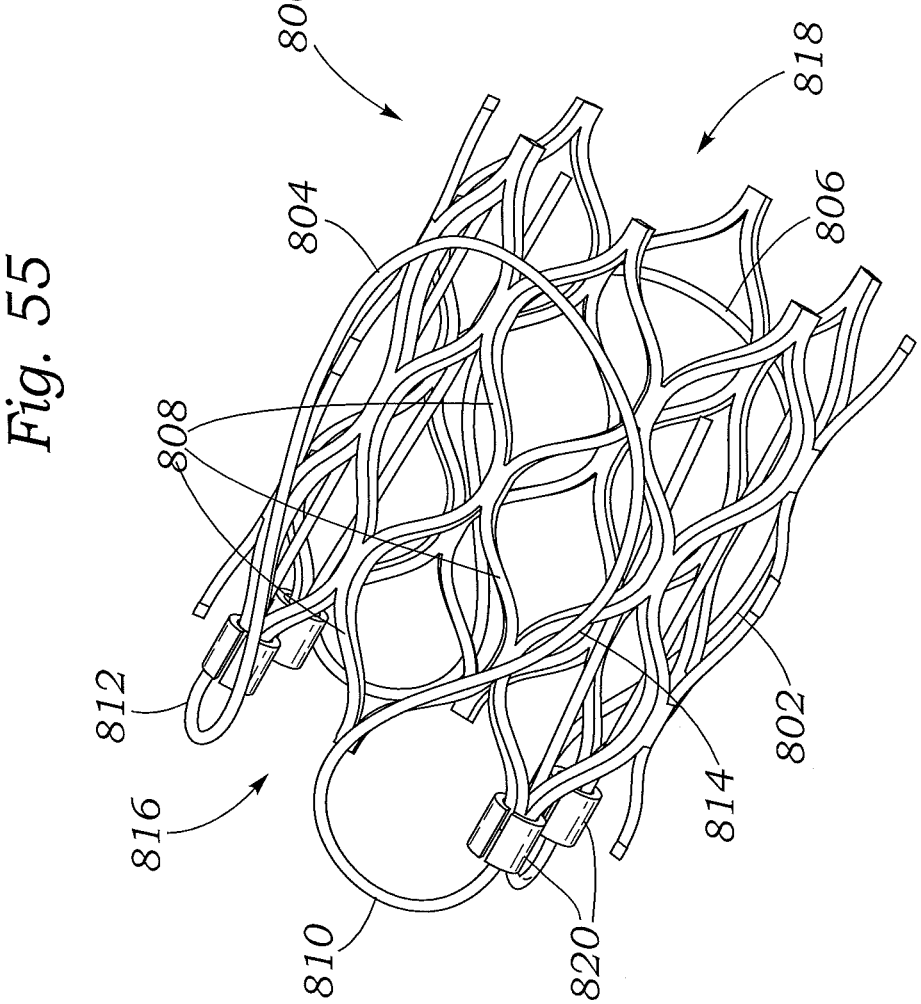


Fig. 55

Fig. 58

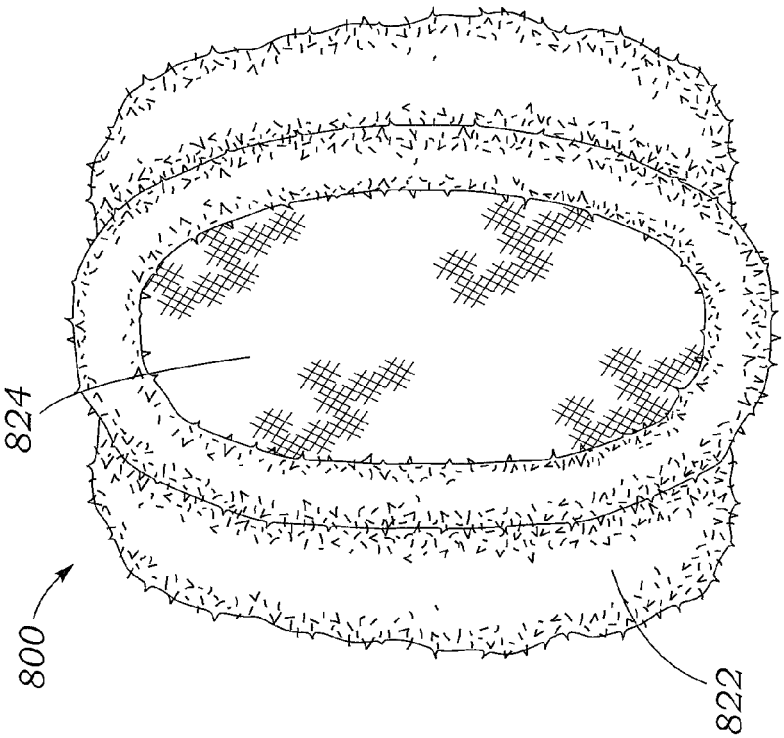
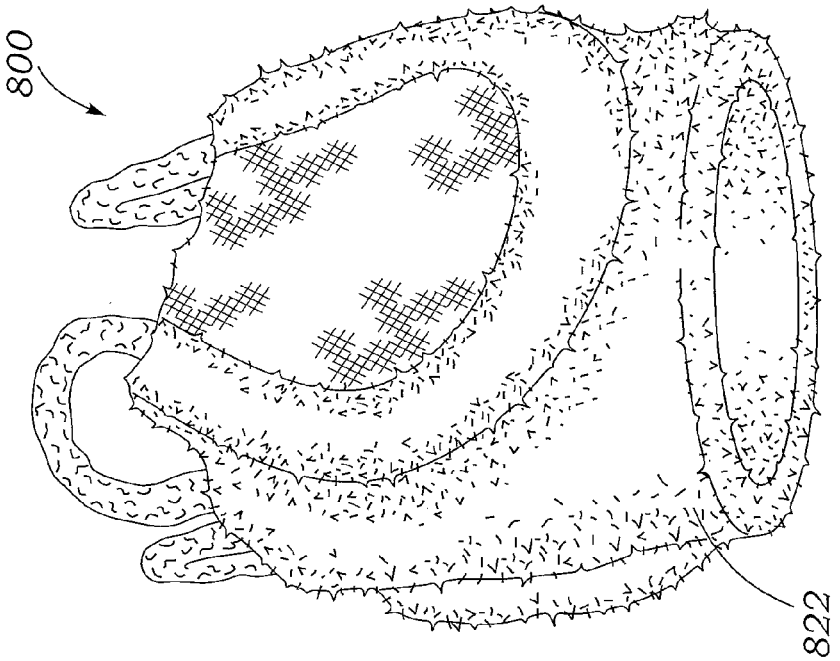


Fig. 57



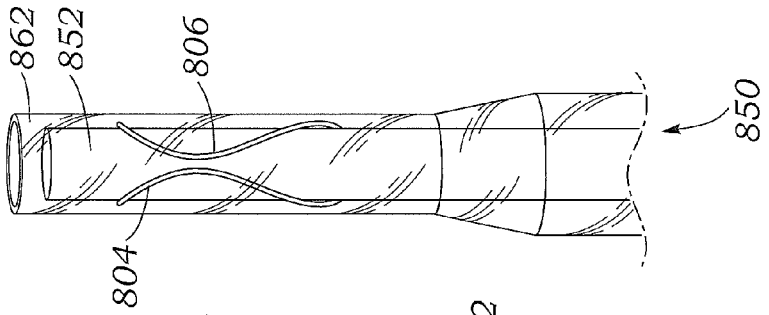


Fig. 61

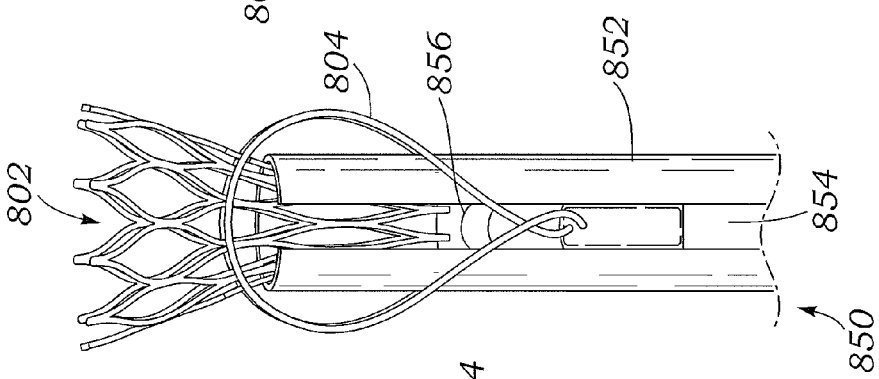


Fig. 60

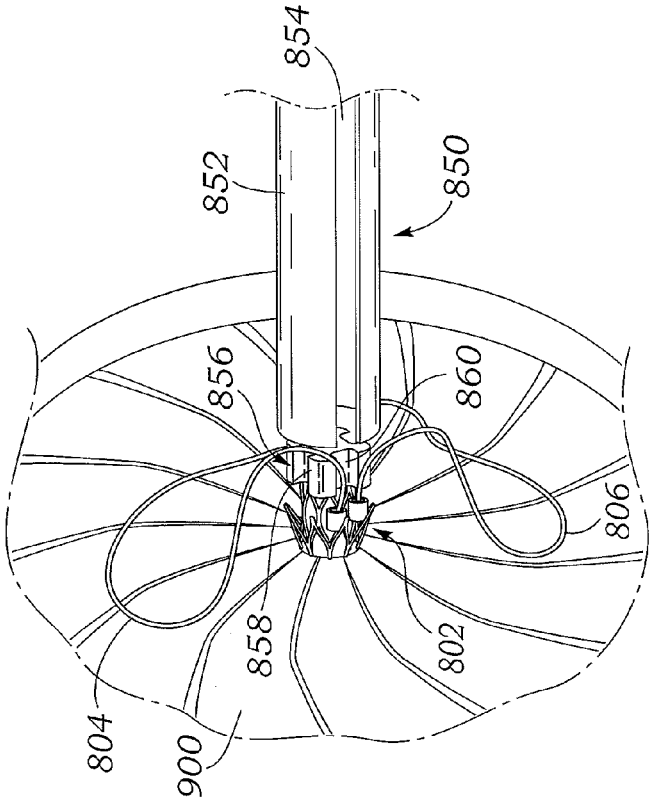


Fig. 59

Fig. 62

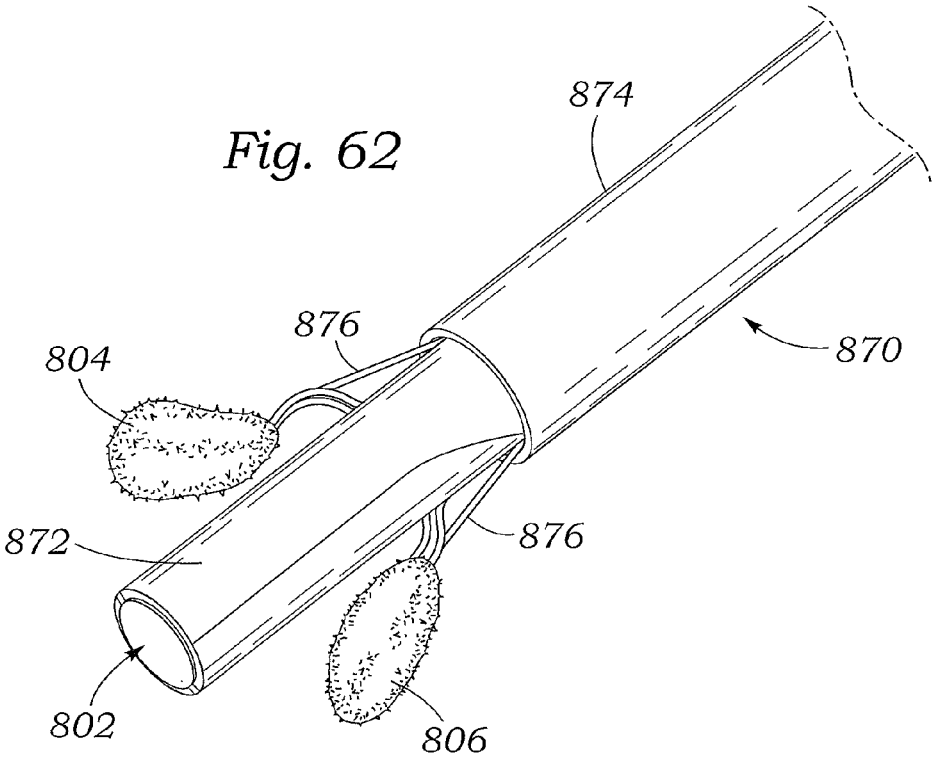


Fig. 63

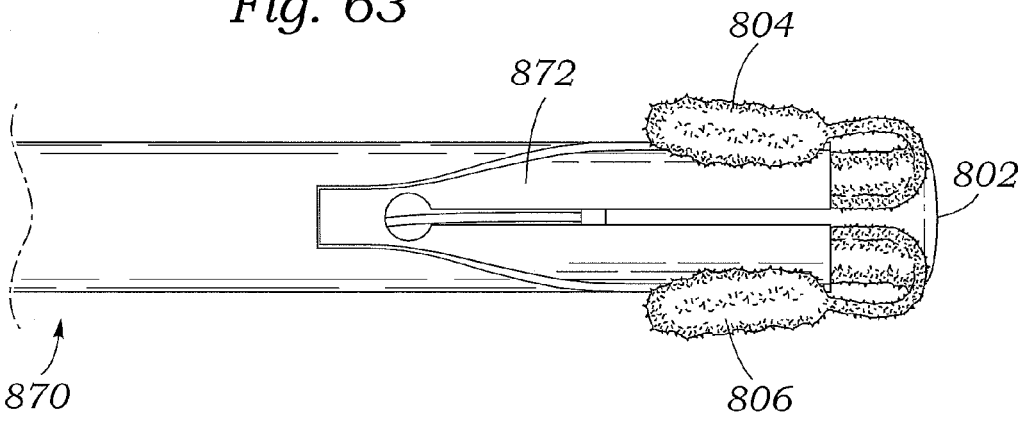


Fig. 64

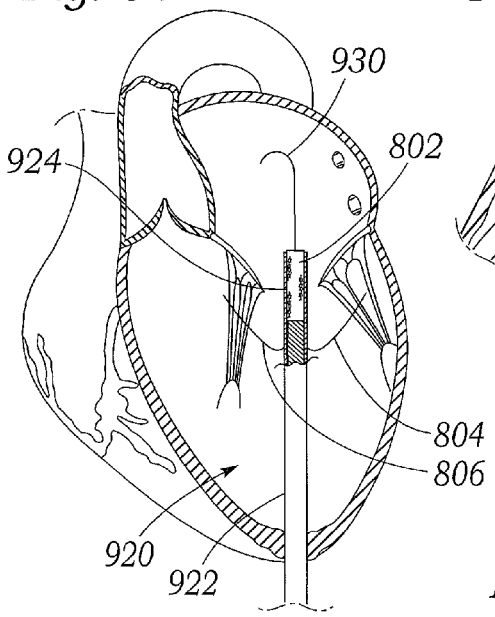


Fig. 65

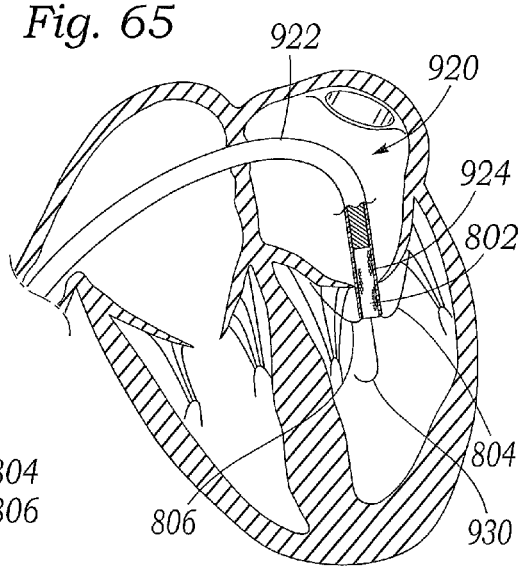


Fig. 66

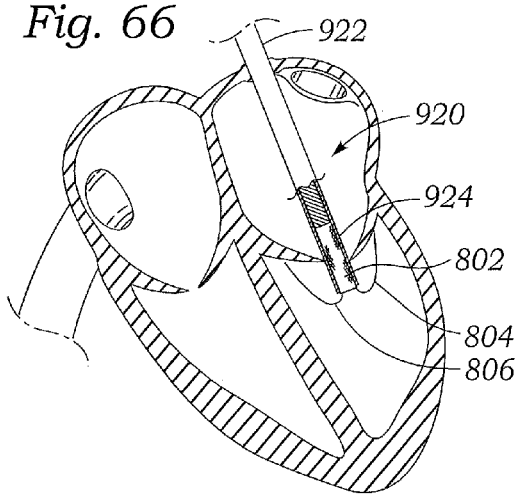


Fig. 67

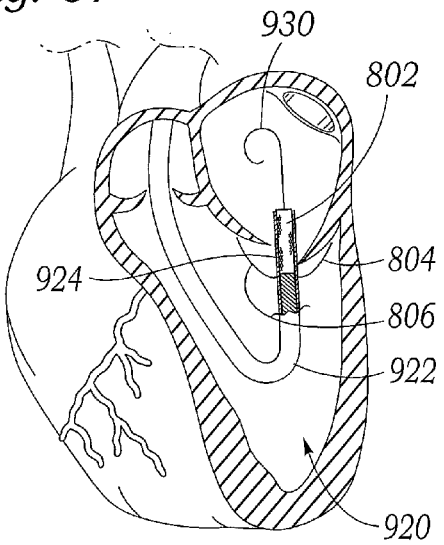
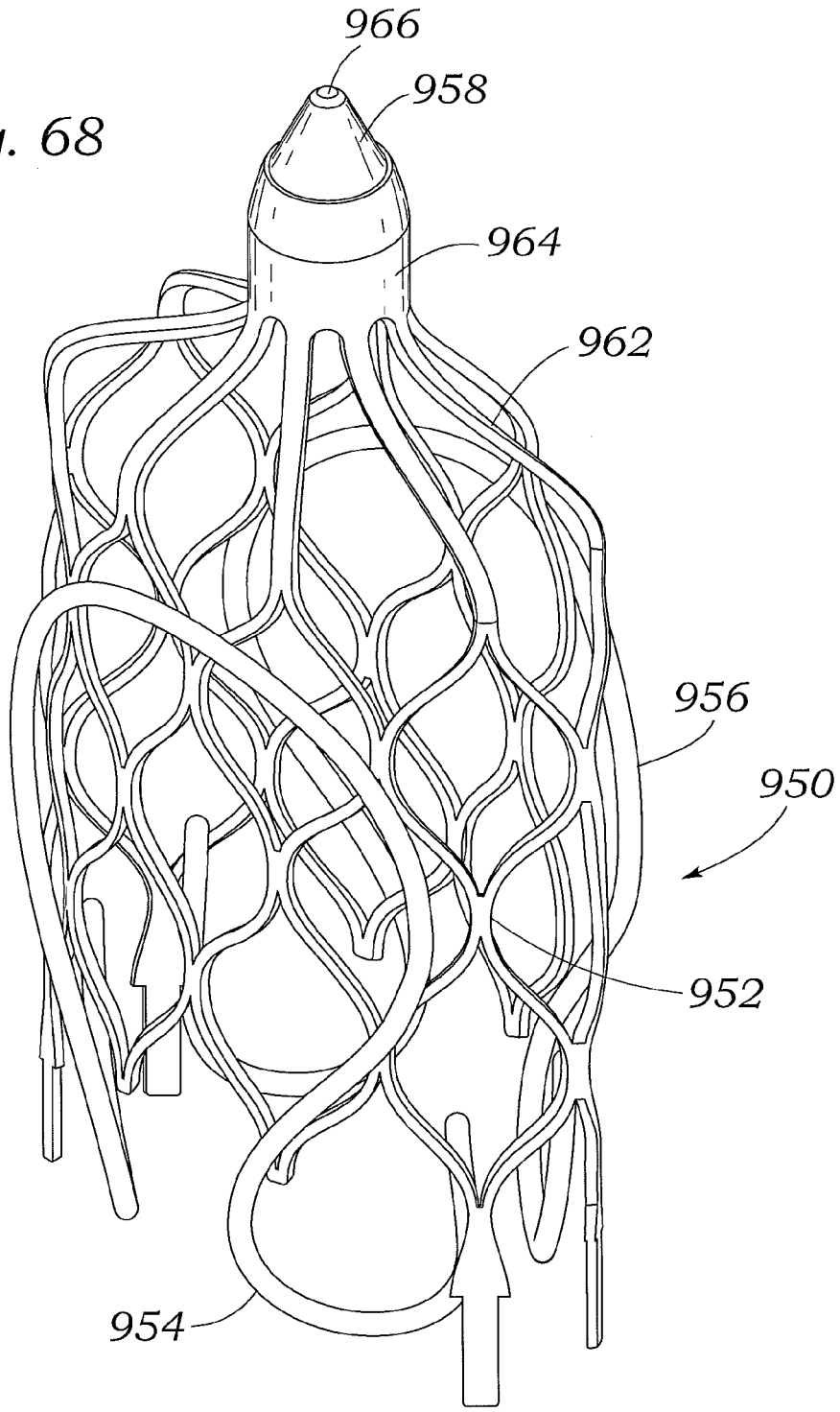


Fig. 68



HEART VALVE SEALING DEVICES

CROSS REFERENCE TO RELATED APPLICATIONS

This application claims the benefit of U.S. Provisional Patent Application No. 61/697,706, filed Sep. 6, 2012, and 61/763,848, filed Feb. 12, 2013, which are each hereby incorporated herein by reference in their entirety.

FIELD

This disclosure pertains generally to prosthetic devices and related methods for helping to seal native heart valves and prevent or reduce regurgitation therethrough, as well as devices and related methods for implanting such prosthetic devices.

BACKGROUND

The native heart valves (i.e., the aortic, pulmonary, tricuspid and mitral valves) serve critical functions in assuring the forward flow of an adequate supply of blood through the cardiovascular system. These heart valves can be rendered less effective by congenital malformations, inflammatory processes, infectious conditions or disease. Such damage to the valves can result in serious cardiovascular compromise or death. For many years the definitive treatment for such disorders was the surgical repair or replacement of the valve during open heart surgery. However, such surgeries are highly invasive and are prone to many complications. Therefore, elderly and frail patients with defective heart valves often went untreated. More recently, transvascular techniques have been developed for introducing and implanting prosthetic devices in a manner that is much less invasive than open heart surgery. Such transvascular techniques have increased in popularity due to their high success rates.

A healthy heart has a generally conical shape that tapers to a lower apex. The heart is four-chambered and comprises the left atrium, right atrium, left ventricle, and right ventricle. The left and right sides of the heart are separated by a wall generally referred to as the septum. The native mitral valve of the human heart connects the left atrium to the left ventricle. The mitral valve has a very different anatomy than other native heart valves. The mitral valve includes an annulus portion, which is an annular portion of the native valve tissue surrounding the mitral valve orifice, and a pair of cusps, or leaflets extending downward from the annulus into the left ventricle. The mitral valve annulus can form a "D" shaped, oval, or otherwise out-of-round cross-sectional shape having major and minor axes. The anterior leaflet can be larger than the posterior leaflet, forming a generally "C" shaped boundary between the abutting free edges of the leaflets when they are closed together.

When operating properly, the anterior leaflet and the posterior leaflet function together as a one-way valve to allow blood to flow only from the left atrium to the left ventricle. The left atrium receives oxygenated blood from the pulmonary veins. When the muscles of the left atrium contract and the left ventricle dilates, the oxygenated blood that is collected in the left atrium flows into the left ventricle. When the muscles of the left atrium relax and the muscles of the left ventricle contract, the increased blood pressure in the left ventricle urges the two leaflets together, thereby closing the one-way mitral valve so that blood cannot flow back to the left atrium and is instead expelled out of the left ventricle through the aortic valve. To prevent the two leaflets from prolapsing under pressure and folding back through the mitral annulus toward the left atrium, a plurality of fibrous cords called chordae tendineae tether the leaflets to papillary muscles in the left ventricle.

Mitral regurgitation occurs when the native mitral valve fails to close properly and blood flows into the left atrium from the left ventricle during the systole phase of heart contraction. Mitral regurgitation is the most common form of valvular heart disease. Mitral regurgitation has different causes, such as leaflet prolapse, dysfunctional papillary muscles and/or stretching of the mitral valve annulus resulting from dilation of the left ventricle. Mitral regurgitation at a central portion of the leaflets can be referred to as central jet mitral regurgitation and mitral regurgitation nearer to one commissure (i.e., location where the leaflets meet) of the leaflets can be referred to as eccentric jet mitral regurgitation.

Some prior techniques for treating mitral regurgitation include stitching portions of the native mitral valve leaflets directly to one another. Other prior techniques include the use of a spacer implanted between the native mitral valve leaflets. Despite these prior techniques, there is a continuing need for improved devices and methods for treating mitral valve regurgitation.

SUMMARY

This disclosure pertains generally to prosthetic devices and related methods for helping to seal native heart valves and prevent or reduce regurgitation therethrough, as well as devices and related methods for implanting such prosthetic devices.

In some embodiments, a prosthetic device for treating heart valve regurgitation comprises a radially compressible and radially expandable body having a first end, a second end, and an outer surface extending from the first end to the second end and an anchor having a connection portion and a leaflet capture portion, wherein the connection portion is coupled to the body such that the leaflet capture portion is biased against the outer surface of the body when the body is in a radially expanded state, the prosthetic device is configured to capture a leaflet of a native heart valve between the leaflet capture portion of the anchor and the outer surface of the body, and the body is configured to prevent blood from flowing through the body in a direction extending from the first end to the second end and in a direction extending from the second end to the first end.

In some embodiments, the outer surface of the body comprises a first side against which the anchor is biased and a second side opposite the first side, and the connection portion of the anchor is coupled to the body on the second side of the body. In some embodiments, the anchor comprises an elongated member that is coupled to the second side of the body at a connection location and the elongated member comprises a ventricular portion that extends from the connection location across the first end of the body. In some embodiments, the ventricular portion comprises first and second ventricular portions and the first ventricular portion is substantially parallel to the second ventricular portion.

In some embodiments, the body is radially compressible to a compressed state in which a leaflet-receiving gap exists between the body and the leaflet capture portion of the anchor, and the body is resiliently radially self-expandable to the radially expanded state. In some embodiments, the anchor comprises a first clip portion and a second clip portion, and the device is configured to capture the leaflet between the first and second clip portions. In some embodiments, the body is formed from Nitinol and is radially self-expandable to the

expanded state. In some embodiments, the body comprises a metallic frame and a blood-impermeable fabric mounted on the frame. In some embodiments, the body is configured to allow blood to flow around the body between the body and a non-captured leaflet during diastole, and configured to allow the non-captured leaflet to close around the body to prevent mitral regurgitation during systole.

In some embodiments, the anchor is coupled to the first end of the body and the device further comprises an atrial stabilizing member extending from the second end of the body. In some embodiments, the body is configured to move within the native heart valve along with motion of the captured leaflet. In some embodiments, an atrial end portion of the body comprises a tapered shoulder that reduces in diameter moving toward the atrial end portion of the body. In some embodiments, the body comprises a crescent cross-sectional shape. In some embodiments, the anchor comprises first and second anchors and the device is configured to be secured to both native mitral valve leaflets.

In some embodiments, a prosthetic device for treating heart valve regurgitation comprises a main body portion having a connection portion and a free end portion, wherein the connection portion is configured to be coupled to a first one of the two native mitral valve leaflets such that the device is implanted within a native mitral valve orifice, and when the device is implanted within the native mitral valve orifice, the free end portion moves laterally toward a second one of the two native mitral valve leaflets during systole, thereby helping to seal the orifice and reduce mitral regurgitation during systole, and the free end portion moves laterally away from the second native mitral valve leaflet during diastole to allow blood to flow from the left atrium to the left ventricle during diastole.

In some embodiments, the connection portion of the main body is thicker than the free end portion. In some embodiments, the main body portion further comprises an atrial portion that contacts the native mitral valve annulus within the left atrium adjacent to the first native mitral valve leaflet. In some embodiments, the device further comprises a ventricular anchor that clips around a lower end of the first native mitral valve leaflet, thereby securing the device to the first native mitral valve leaflet. In some embodiments, the anchor comprises a paddle shape with a broad upper end portion and a relatively narrow neck portion, wherein the neck portion couples the upper end portion to the main body.

In some embodiments, a prosthetic device comprises a sheet of flexible, blood-impermeable material configured to be implanted within a native mitral valve orifice and coupled to a first one of the two native mitral leaflets or to the native mitral annulus adjacent the first native mitral leaflet, wherein when implanted the sheet is configured to inflate with blood during systole such that a free portion of the sheet not coupled to the first native mitral leaflet or the mitral annulus adjacent the first native mitral leaflet moves laterally toward and seals against the second of the two native mitral leaflets to reduce mitral regurgitation, and when implanted the sheet is configured to deflate during diastole such that the portion of the sheet not coupled to the first native mitral leaflet or the native mitral annulus adjacent the first native mitral leaflet moves laterally away from the second native mitral leaflet to allow blood to flow from the left atrium to the left ventricle.

In some embodiments, the sheet is supported by a rigid frame that is secured to the first native mitral leaflet. In some embodiments, the frame comprises a ventricular anchor that clips around a lower end of the first native mitral leaflet. In some embodiments, the frame comprises an atrial portion that contacts the native mitral annulus within the left atrium adjacent to the first native mitral leaflet. In some embodiments, an upper end of the sheet is secured directly to the native mitral annulus adjacent the first native mitral leaflet or to the first native mitral leaflet adjacent the native mitral annulus. In some embodiments, the upper end of the sheet is secured to native tissue via rigid anchors that puncture the native tissue.

In some embodiments, the sheet comprises an annular cross-sectional profile perpendicular to an axis extending through the mitral orifice from the left atrium to the left ventricle. In some embodiments, the sheet comprises a closed atrial end and an open ventricular end. In some embodiments, the open lower end is biased toward an open position and is configured to collapse to a closed position during diastole. In some embodiments, the sheet is supported by a rigid frame that is secured to the first native mitral leaflet, and the frame comprises a plurality of longitudinal splines extending from the upper end of the sheet to the lower end of the sheet. In some embodiments, the splines are biased to cause the lower end of the sheet to open away from the first native leaflet.

In some embodiments, a lower end of the sheet is tethered to a location in the left ventricle below the native mitral leaflets. In some embodiments, the lower end of the sheet is tethered to the papillary muscle heads in the left ventricle. In some embodiments, the lower end of the sheet is tethered to a lower end of the rigid frame. In some embodiments, opposing lateral ends of the lower end of the sheet are tethered to the lower end of the frame such that an intermediate portion of the lower end of the sheet can billow out away from the frame and toward the second leaflet during systole. In some embodiments, the sheet has a generally trapezoidal shape, with a broader portion adjacent to the mitral annulus and a narrower portion positioned between the native mitral leaflets.

In some embodiments, a prosthetic device for treating heart valve regurgitation comprises a radially compressible and radially expandable body having a first end, a second end, and an outer surface extending from the first end to the second end, a first anchor coupled to the body and configured to capture the anterior native mitral valve leaflet between the first anchor and the body to secure the device to the anterior leaflet, and a second anchor coupled to the body and configured to capture the posterior native mitral valve leaflet between the second anchor and the body to secure the device to the posterior leaflet, wherein when the first and second anchors capture the anterior and posterior leaflets, the body is situated within a mitral valve orifice between the anterior and posterior leaflets, thereby decreasing a size of the orifice.

In some embodiments, the body is radially compressible to a collapsed delivery configuration suitable for delivering the device to the native mitral valve, and radially expandable from the collapsed delivery configuration to an expanded, operational configuration suitable for operation in the native mitral valve. In some embodiments, the body is formed from Nitinol and is radially self-expandable from the collapsed configuration to the expanded configuration. In some embodiments, the device further comprises a sheet of blood impermeable fabric covering the body. In some embodiments, the body has an elliptical cross-sectional shape. In some embodiments, the body has a crescent cross-sectional shape. In some embodiments, the body comprises a prosthetic valve. In some embodiments, the body is configured to prevent blood from flowing through the body in a direction extending from the first end to the second end and in a direction from the second end to the first end.

In some embodiments, a method of implanting a prosthetic sealing device at a native mitral valve of a heart comprises advancing a delivery catheter to a native mitral valve region of a heart from a left atrium of the heart, the delivery catheter

housing the prosthetic sealing device in a radially compressed configuration, advancing the prosthetic sealing device distally relative to the delivery catheter such that an anchor of the prosthetic sealing device moves out of the catheter and forms a leaflet-receiving gap between an end portion of the anchor and the delivery catheter, positioning either a posterior or an anterior mitral valve leaflet in the gap, and advancing a radially compressed body of the prosthetic sealing device out of the delivery catheter such that the body self-expands radially toward the end portion of the anchor, reducing the gap, and capturing the leaflet between the body and the end portion of the anchor, wherein the body is configured to prevent the flow of blood through the body during systole and during diastole.

In some embodiments, a non-captured one of the anterior and posterior leaflets is not secured to the prosthetic sealing device when the prosthetic sealing device is implanted at the native mitral valve. In some embodiments, advancing a delivery catheter through the native mitral valve from a left atrium comprises advancing the delivery catheter through an incision in a portion of a septum between the left atrium and a right atrium. In some embodiments, when the delivery catheter is advanced to the native mitral valve region of the heart, the anchor is held in a substantially straightened position within the delivery catheter extending distally from body of the prosthetic sealing device.

In some embodiments, a method of implanting a prosthetic sealing device at a native mitral valve comprises advancing a delivery device to a native mitral valve region via a left ventricle, the delivery catheter housing the prosthetic sealing device in a compressed configuration, allowing an anchor of the prosthetic sealing device to move radially out of the delivery device while a body of the delivery device is in a compressed configuration, such that a leaflet-receiving gap forms between an end portion of the anchor and the delivery device, positioning either a posterior or an anterior mitral valve leaflet in the gap, and allowing the body of the prosthetic sealing device to radially self-expand such that the leaflet is captured between the body and the anchor, wherein the body is configured to prevent the flow of blood through the body during systole and during diastole.

In some embodiments, a non-captured one of the anterior and posterior mitral valve leaflets is not secured to the prosthetic sealing device when the prosthetic sealing device is implanted at the native mitral valve. In some embodiments, advancing a delivery device to a native mitral valve region via a left ventricle comprises inserting the delivery device into the left ventricle through an incision in an apex of the left ventricle.

In some embodiments, a method of implanting a prosthetic sealing device at a native mitral valve of a heart comprises advancing a delivery system to a native mitral valve region of a heart from a left ventricle of the heart, the delivery system housing the prosthetic sealing device in a radially compressed configuration, proximally retracting an outer sheath of the delivery system such that anchors of the prosthetic sealing device are not confined within the delivery system, advancing the delivery system toward the left atrium of the heart such that native mitral valve leaflets are positioned between the anchors of the prosthetic sealing device and the delivery system, proximally retracting an inner sheath of the delivery system such that a body of the prosthetic sealing device is not confined within the delivery system, wherein the body is configured to prevent the flow of blood through the body during systole and during diastole, and removing the delivery system from the native mitral valve region of the heart.

In some embodiments, advancing the delivery system to the native mitral valve region from the left ventricle comprises inserting the delivery device into the left ventricle through an incision in an apex of the left ventricle. In some embodiments, when the delivery system is advanced to the native mitral valve region of the heart, the anchor is held in a substantially straightened position within the delivery catheter extending distally along a side of the body of the prosthetic sealing device.

In some embodiments, a method of implanting a prosthetic sealing device at a native mitral valve of a heart comprises advancing a delivery system to a native mitral valve region of a heart from a left atrium of the heart, the delivery system housing the prosthetic sealing device in a radially compressed configuration, proximally retracting an outer sheath of the delivery system such that anchors of the prosthetic sealing device are not confined within the delivery system, retracting the delivery system toward the left atrium of the heart such that native mitral valve leaflets are positioned between the anchors of the prosthetic sealing device and the delivery system, proximally retracting an inner sheath of the delivery system such that a body of the prosthetic sealing device is not confined within the delivery system, wherein the body is configured to prevent the flow of blood through the body during systole and during diastole, and removing the delivery system from the native mitral valve region of the heart.

In some embodiments, advancing the delivery system to the native mitral valve region from the left atrium comprises advancing the delivery system through an incision in a portion of a septum between the left atrium and a right atrium. In some embodiments, when the delivery system is advanced to the native mitral valve region of the heart, the anchor is held in a substantially straightened position within the delivery catheter extending proximally from body of the prosthetic sealing device.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** shows a portion of a human heart with an exemplary embodiment of a sealing device attached to the native posterior mitral leaflet.

FIG. **2** shows a portion of a human heart with an exemplary embodiment of a sealing device attached to the native anterior mitral leaflet.

FIG. **3** shows a portion of a human heart with an exemplary embodiment of a sealing device attached to the native posterior mitral leaflet and having an atrial anchor.

FIG. **4** is an atrial end view of one embodiment of the sealing device of FIG. **3** having a lattice-type atrial anchor.

FIG. **5** is an atrial end view of another embodiment of the sealing device of FIG. **3** having a loop-type atrial anchor.

FIG. **6** is a side view of an exemplary sealing device.

FIG. **7** is another side view of the sealing device of FIG. **6**.

FIG. **8** is an atrial end view of the sealing device of FIG. **6**.

FIG. **9** is an atrial end view of the sealing device of FIG. **6** implanted at a native mitral valve.

FIG. **10** shows a crescent-shaped embodiment of a sealing device.

FIG. **11** shows a sealing device having an anchor that extends from one side of a body, around a ventricular end of the body, and along a second side of the body.

FIGS. **12-15** show a method of deploying the sealing device of FIG. **11** from a delivery sheath.

FIG. **16** is a side view of another embodiment of a sealing device having an anchor that extends from one side of a body, around a ventricular end of the body, and along a second side of the body.

FIG. **17** is another side view of the embodiment of FIG. **16**.

FIG. **18** is an atrial end view of the embodiment of FIG. **16**.

FIG. **19** is a side view of an embodiment similar to that shown in FIG. **16**.

FIG. **20** shows the embodiment of FIG. **19** covered with a fabric layer.

FIG. **21** is a ventricular end view of the embodiment of FIG. **20** implanted at a native mitral valve.

FIG. **22** shows a portion of a human heart with an exemplary sealing device being implanted at the mitral region in a transeptal approach.

FIG. **23** shows a portion of a human heart with an exemplary sealing device being implanted at the mitral region in a transapical approach.

FIG. **24** shows a human heart with an exemplary prosthetic device attached to a native mitral leaflet.

FIG. **25** shows an exemplary prosthetic device being coupled to a native mitral leaflet in a transeptal approach.

FIG. **26** shows an exemplary prosthetic device being coupled to a native mitral leaflet in a transapical approach.

FIGS. **27** and **28** show another exemplary prosthetic device being coupled to a native mitral leaflet.

FIGS. **29-31** show an exemplary prosthetic device attached to the mitral valve region of a human heart.

FIGS. **32-34** show another exemplary prosthetic device attached to the mitral valve region of a human heart.

FIG. **35** shows two exemplary prosthetic devices, each being coupled to a respective one of the native mitral valve leaflets.

FIG. **36** shows two exemplary prosthetic devices, each being coupled to a respective one of the native mitral valve leaflets.

FIG. **37** shows two exemplary prosthetic devices, each being coupled to a respective one of the native mitral valve leaflets.

FIGS. **38-41** show an exemplary prosthetic device having two anchors.

FIG. **42** shows an exemplary prosthetic device having two anchors, coupled to both of the native mitral valve leaflets.

FIG. **43** shows an exemplary prosthetic device having two anchors, coupled to both of the native mitral valve leaflets, from an atrial view.

FIG. **44** shows an exemplary prosthetic device having an elongated body and two anchors, coupled to both of the native mitral valve leaflets, from an atrial view.

FIG. **45** shows an exemplary prosthetic device having a valve and two anchors, coupled to both of the native mitral valve leaflets, from an atrial view.

FIG. **46** shows an exemplary prosthetic device having a crescent-shaped body and two anchors, coupled to both of the native mitral valve leaflets, from an atrial view.

FIGS. **47-51** show exemplary prosthetic devices having three anchors.

FIGS. **52-54** show the prosthetic device of FIGS. **38-41** implanted at a native mitral valve.

FIGS. **55** and **56** show another exemplary prosthetic device comprising a radially compressible and expandable body.

FIGS. **57** and **58** show the prosthetic device of FIGS. **55** and **56** with a fabric layer.

FIGS. **59-63** show an exemplary prosthetic device with an exemplary delivery system, in various configurations.

FIGS. **64-67** show various exemplary delivery approaches for delivering a prosthetic device to a native mitral valve.

FIG. **68** shows an exemplary prosthetic device including a nosecone.

DETAILED DESCRIPTION

Described herein are embodiments of prosthetic devices that are primarily intended to be implanted at one of the mitral, aortic, tricuspid, or pulmonary valve regions of a human heart, as well as apparatuses and methods for implanting the same. The prosthetic devices can be used to help restore and/or replace the functionality of a defective native mitral valve. The disclosed embodiments should not be construed as limiting in any way. Instead, the present disclosure is directed toward all novel and nonobvious features and aspects of the various disclosed embodiments, alone and in various combinations and sub-combinations with one another.

Prosthetic Spacers

In some embodiments, a prosthetic device comprises a body and an anchor. The body is configured to be positioned within the native mitral valve orifice to help create a more effective seal between the native leaflets to prevent or minimize mitral regurgitation. The body can comprise a structure that is impervious to blood and that allows the native leaflets to close around the sides of the body during ventricular systole to block blood from flowing from the left ventricle back into the left atrium. The body is sometimes referred to herein as a spacer because the body can fill a space between improperly functioning native mitral leaflets that do not naturally close completely. In some embodiments, the body can comprise a prosthetic valve structure positioned within an annular body.

The body can have various shapes. In some embodiments, the body can have an elongated cylindrical shape having a round cross-sectional shape. In other embodiments, the body can have an ovular cross-sectional shape, a crescent cross-sectional shape, or various other non-cylindrical shapes. The body can have an atrial or upper end positioned in or adjacent to the left atrium, a ventricular or lower end positioned in or adjacent to the left ventricle, and an annular side surface that extends between the native mitral leaflets.

The anchor can be configured to secure the device to one or both of the native mitral leaflets such that the body is positioned between the two native leaflets. The anchor can attach to the body at a location adjacent the ventricular end of the body. The anchor can be configured to be positioned behind a native leaflet when implanted such that the leaflet is captured between the anchor and the body.

The prosthetic device can be configured to be implanted via a delivery sheath. The body and the anchor can be compressible to a radially compressed state and can be self-expandable to a radially expanded state when compressive pressure is released. The device can be configured to allow the anchor to self-expand radially away from the still-compressed body initially in order to create a gap between the body and the anchor. The leaflet can then be positioned in the gap. The body can then be allowed to self-expand radially, closing the gap between the body and the anchor and capturing the leaflet between the body and the anchor. The implantation methods for various embodiments can be different, and are more fully discussed below with respect to each embodiment. Additional information regarding these and other delivery methods can be found in U.S. Patent Application Publication No. 2011/0137397 and U.S. Provisional Patent Application No. 61/760,577, which are incorporated by reference herein in their entirety.

Some embodiments disclosed herein are generally configured to be secured to only one of the native mitral leaflets. However, other embodiments comprise more than one anchor and can be configured to be secured to both mitral leaflets. Unless otherwise stated, any of the embodiments disclosed herein that comprise a single anchor can optionally be secured to the anterior mitral leaflet or secured to the posterior

mitral leaflet, regardless of whether the particular embodiments are shown as being secured to a particular one of the leaflets.

Furthermore, some embodiments can optionally also include one or more atrial anchors, such as to provide additional stabilization. Unless otherwise stated, any of the embodiments disclosed herein can optionally include an atrial anchor or not include an atrial anchor, regardless of whether the particular embodiments are shown with an atrial anchor or not.

Some of the disclosed prosthetic devices are prevented from atrial embolization by having the anchor hooked around a leaflet, utilizing the tension from native chordae tendinae to resist high systolic pressure urging the device toward the left atrium. During diastole, the devices can rely on the compressive forces exerted on the leaflet that is captured between the body and the anchor to resist embolization into the left ventricle.

FIG. **1** shows an exemplary embodiment of a prosthetic device **10** that comprises a body **12** and an anchor **14**. The device **10** is secured to the posterior mitral leaflet **8** with the free end of the leaflet **8** captured between the anchor **14** and the body **12**. In FIG. **1**, the anterior mitral leaflet **6** is shown separated from the body **12** during diastole as blood flows from the left atrium **2** into the left ventricle **4**. As the mitral leaflets open apart from each other, the device **10** can move with the posterior leaflet **8**, allowing the anterior leaflet **6** to open away from the body **12**. During systole, the back pressure on the leaflets closes them together around the body **12** to prevent mitral regurgitation. FIG. **2** shows the device **10** alternatively secured to the anterior mitral leaflet **6** with the posterior mitral leaflet **8** free to articulate toward and away from the device **10**.

FIG. **3** shows a prosthetic device **20** having a body **22**, a ventricular anchor **24**, and an atrial anchor **26**. The device **20** is shown secured to the posterior leaflet **8** via the ventricular anchor **24**. The atrial anchor **26** can extend laterally from adjacent the atrial end of the body **22** toward the mitral annulus or other lateral portions of the left atrium **2** adjacent to the posterior leaflet **8**. The atrial anchor **26** can help stabilize the device. For example, the atrial anchor **26** can prevent the body **22** from tilting and keep it oriented longitudinally along the blood flow direction through the mitral orifice. The atrial anchor **26** can also help prevent the device **20** from embolizing into the left ventricle **4**.

FIGS. **4** and **5** are atrial end views showing two alternative embodiments of atrial anchors for the device **20**. FIG. **4** shows an atrial anchor **26**A that comprises a lattice-type framework supported by two connections to the body **22**, while FIG. **5** shows an atrial anchor **26**B that comprises a single elongated member extending in a loop between two connections to the body **22**. In both embodiments, the atrial anchor comprises a relatively broader or wider end portion configured to engage with the atrial tissue so as to spread out the engagement forces to avoid tissue damage and promote increased tissue ingrowth.

FIGS. **6-8** show three views of an exemplary embodiment of the prosthetic device **20** having a cylindrical body **22**, a ventricular anchor **24**, and an atrial anchor **26**C. The ventricular anchor **24**, as shown in FIGS. **6** and **7**, comprises an elongated member that extends from two connection points adjacent the ventricular end of the body **22** and along one side of the body toward the atrial end of the body. The ventricular anchor is contoured around the generally cylindrical side surface of the body **22**. The atrial anchor **26**C comprises a lattice-type framework made up of several diamond-shaped segments **29** coupled side-by-side in an arc. The atrial anchor **26**C further comprises three connecting members **27** coupling it to the body **22** adjacent the atrial end of the body. As shown in FIG. **6**, the atrial member **26**C extends generally laterally to the same side of the body **22** as the ventricular anchor **24**. The radially outward end portion of the atrial anchor can have an upward curvature to conform to the curved geometry of the left atrium. Each of the diamond-shaped segments **29** comprises radially outwardly pointing tip **30** that can press into and/or penetrate adjacent tissue in some cases.

The device **20** is shown in an expanded configuration in FIGS. **3-9**. In a compressed delivery configuration, the atrial anchor **26** can be folded down against the side of the body **22** or extended upwardly away from the body **22**. Furthermore, the atrial anchor **26** can be circumferentially compressed, especially embodiments having a lattice-type structure.

The body **22** can comprise an annular metal frame **32** covered with a blood-impervious fabric **28**, as shown in FIGS. **6-9**. One or both ends of the body can also be covered with the blood-impervious fabric **28**, as shown in FIG. **8**. The frame **32** can comprise a mesh-like structure comprising a plurality of interconnected metal struts, like a conventional radially compressible and expandable stent. In other embodiments, the body can comprise a solid block of material, such as flexible sponge-like block. In some embodiments, the body **22** can be hollow or filled with material.

The frame **32** can be formed from a self-expandable material, such as Nitinol. When formed from a self-expandable material, the frame **32** can be radially compressed to a delivery configuration and can be retained in the delivery configuration by placing the device in the sheath of a delivery apparatus. When deployed from the sheath, the frame **32** can self-expand to its functional size. In other embodiments, the frame can be formed from a plastically expandable material, such as stainless steel or a cobalt chromium alloy. When formed from a plastically expandable material, the prosthetic device can be crimped onto a delivery apparatus and radially expanded to its functional size by an inflatable balloon or an equivalent expansion mechanism. It should be noted that any of the embodiments disclosed herein can comprise a self-expandable main body or a plastically expandable main body.

FIG. **9** is a view from the left atrium **2** of the device **20** of FIGS. **6-8** implanted at a mitral valve. The body **22** is positioned between the native leaflets **6**, **8** in a sealed position with the atrial anchor **26**C engaged with the atrial tissue adjacent the posterior mitral leaflet **8**. The atrial end of the body **22** is open while the ventricular end of the body is covered with the impervious fabric **28**.

FIG. **10** shows an exemplary prosthetic device **34** having a crescent shaped body **36**. The body **36** is configured to be positioned with the convex side facing the posterior mitral leaflet **8** and the concave side facing the anterior mitral leaflet **6**. In this embodiment, the body **36** can comprise a flexible, sponge-like material. Consequently, the device **34** can comprise two ventricular anchors to capture the anterior leaflet **6**. A first ventricular anchor **44** is configured to be positioned behind the anterior leaflet while a second ventricular anchor **42** is configured to be positioned between the body **36** and the anterior leaflet. The anterior leaflet **6** is therefore captured and pinched between the two anchors **42**, **44** to secure the body **36** within the mitral orifice. The device **34** relies on the two anchors **42**, **44** to capture the leaflet because the body **36** in this embodiment may lack sufficient rigidity to grip the leaflet. Both of the ventricular anchors **42**, **44** can extend from adjacent a ventricular end **40** of the body **36** and extend up toward an atrial end **38** of the body along the same side of the body. In other embodiments, the anchors **42**, **44** can be posi-

tioned on the convex side of the body **36** in order to secure the body to the posterior leaflet. In some embodiments, the anchor **42** can be nested within the anchor **44** to provide a smaller crimped profile. In other embodiments, the anchors **42**, **44** can have various other shapes. In still other embodiments, the body **36** can be cylindrical or can have any of various other shapes described herein.

FIG. **11** shows an exemplary embodiment of a prosthetic device **50** having a body **52** and an anchor **54** that attaches to a first side of the body, extends around the ventricular end of the body, and extends along a second side of the body opposite the first side of the body. The device **50** is configured to capture a mitral leaflet between the anchor **54** and the second side of the body **52** to secure the body within the mitral orifice. The body **52** can comprise, for example, a radially compressible and expandable metal stent covered by a blood impermeable fabric, as described above.

FIGS. **12-15** illustrate an exemplary method of deployment of the device **50** from a delivery catheter **56**. In FIG. **12**, the body **52** is shown in a radially compressed state within the catheter **56** with the anchor **54** extending distally from the ventricular end of the body in a straightened, or unfurled, state. The device **50** can be resiliently deformed in this configuration such that the device **50** resiliently returns to the configuration shown in FIG. **11** when released from constraint. A pusher member **59** can be used to push the device **50** distally relative to the catheter **56** or to hold the device **50** steady as the catheter is retracted. In FIG. **13**, the catheter **56** is retracted proximally from the device **50** and/or the device **50** is advanced distally from the catheter **56** such that the elongated anchor **54** begins to extend out of the distal outlet **58** of the catheter. As the anchor **54** moves out of the outlet **58**, the anchor begins to naturally return toward the shape of FIG. **11**, curling gradually as it is freed from the confining forces of the catheter. In FIG. **14**, the entire anchor **54** has moved out of the catheter **56** and has returned to its natural shape of FIG. **11**. However, the body **52** is still held in radial compression by the catheter, creating a gap **60** between the second side of the body **52** and the end of the anchor **54**. A mitral leaflet can be positioned within the gap **60** while the device is in the configuration of FIG. **14**. In FIG. **15**, the ventricular end **62** of the body **52** begins to advance out of the outlet **58**, allowing the ventricular end **62** of the body to radially expand while the atrial end **64** of the body remains held in compression within the catheter. This causes the body **52** to expand gradually toward the anchor **54**, decreasing the width of the gap **60**, thereby capturing the leaflet within the gap. Once the atrial end **64** of the body **52** is freed from the catheter **56**, the entire body **52** can expand to its fully expanded state shown in FIG. **11**, pinching or compressing the leaflet between the end of the anchor **54** and the side of the body. In the fully expanded state shown in FIG. **11**, a gap remains between the body **52** and the anchor **54**, although the gap is desirably sized such that a leaflet is engaged by the body and the anchor when placed in the gap. In alternative embodiments, however, such a gap may not exist when the device is in its fully expanded state (i.e., the anchor **54** contacts the body **52** when a leaflet is not positioned between these two components).

FIGS. **16-18** show orthogonal views of an exemplary embodiment of a device **70** similar to the device **50**. The device **70** can be deployed from a catheter in the manner described above with respect to FIGS. **11-15**. The device **70** comprises a radially self-expandable body **72** and a ventricular anchor **74**. The body **72** can comprise a narrowed atrial end **76** and a tapered shoulder region **77**, such as to provide improved hemodynamics as blood flows around the shoulder region. The body **72** has a ventricular end **78** opposite from the atrial end **76**. The ventricular anchor **74** can comprise an elongated, curved member that connects to the body **72** at two connection points **80**, **82** adjacent to the ventricular end **78** on a first side of the body (i.e., the right side of the body in FIG. **16**). As shown in FIGS. **16-18**, the anchor **74** comprises first portions **84**, **86** that extend from the connection points **80**, **82**, respectively, around the ventricular end **78** of the body, to a second, opposite side of the body (i.e., the left side of the body in FIG. **16**). The anchor **74** further comprises second portions **88**, **90** that extend from the first portions **84**, **86**, respectively, along the second side of the body toward the atrial end **76** of the body. The second portions **88**, **90** gradually expand apart from each other moving atrially toward an end portion **92** of the anchor **74**. The second portions **88**, **90** and the end portion **92** of the anchor **74** can form a paddle shape, as shown in FIG. **17**, and can have a circumferential curvature that substantially matches the curvature of the body **72**.

Note that, while FIGS. **16-18** appear to show the end portion **92** of the anchor passing within a portion of the body **72**, the end portion **92** actually extends around the outer surface of the body **72**, as shown in FIGS. **19** and **20**. The position of the end portion **92** in FIGS. **16-18** illustrates the position that the anchor **74** wants to resiliently move toward in the absence of resistance from body **72**. When manufactured, the anchor **74** is provided with a pre-bend that causes the end portion **92** to press against the outer surface of the body **72**, as shown in FIGS. **19** and **20**. This provides the device **70** the ability to apply a strong enough clamping force on a leaflet positioned between the end portion **92** and the body **72**, even when the leaflet is very thin.

FIG. **20** also shows a blood-impervious fabric layer **94** covering the body **72** which can prevent blood from flowing through the body **72**. The fabric layer can comprise, for example, polyethylene terephthalate (PET) or polyurethane. Any of the spacers described herein (even if shown just as a frame) can include such a blood-impervious fabric layer covering the spacer, which can prevent blood from flowing through the spacer.

The device **70** can be can be deployed from a delivery catheter according to the method illustrated with respect to device **50** in FIGS. **11-15**, by releasing the anchor **74** first to create a leaflet-receiving gap between the end portion **92** and the body **72**. After positioning a leaflet in the gap, the body **72** can subsequently be freed to self-expand radially toward the end portion **92** to clamp the leaflet between the end portion **92** and the second side of the body **72**.

Because the anchor **74** extends around the ventricular end **78** of the body, the first portions **84**, **86** can be provided with a larger radius of curvature compared to if the anchor **74** was connected to the body **72** on the same side as the end portion **92**. This large radius of curvature of the first portions **84**, **86** can provide greater control over the clamping forces between the end portion **92** and the body **72**, and provide a more robust and durable anchor configuration, reducing stress concentrations in the anchor **74** and connection points **80**, **82**. Because the body is acting as a spacer, causing the blood to flow around it, the anchor **74** can pass around the ventricular end **78** of the body without obstructing the flow of blood any more than necessary. Having the anchor members **84**, **86** positioned below the ventricular end of the body may not be as desirable in embodiments where the body comprises an annular frame with a prosthetic valve within the annular frame, since the members **84**, **86** could restrict the flow of blood through the body to some degree.

In the case of the device **70**, when the device is clipped onto a mitral leaflet between the end portion **92** and the second side of the body **72**, a majority of the blood flow passes around the

other three sides of the body (i.e., the left, right, and bottom side in FIG. **18**). This is illustrated in FIG. **21**, which shows a ventricular end view of the device **70** implanted in a mitral orifice with the posterior leaflet **8** captured between the anchor **74** and the body **72**. The anterior leaflet **6** is opened away from the body **72** in FIG. **21**, allowing blood to flow around three sides of the body during diastole. As shown in FIG. **21**, the first members **84**, **86** of the anchor **74** extend across the body without blocking the flow of blood around the body. Though not shown, during systole, the anterior leaflet **6** can close around the body **72** and create a seal with the body and the side portions of the posterior leaflet **8** to prevent regurgitation into the left atrium **2**. The body **72** is shown in FIG. **21** covered with the blood-impervious fabric **94** that extends around the atrial end **76** of the body and is open on the ventricular end **78** of the body, preventing blood from flowing through the body **72**. In some embodiments, the ventricular end **72** can also be covered by the fabric to fully enclose the body and provide improved hemodynamics.

The exemplary prosthetic devices disclosed herein can be delivered to the mitral region via plural different approaches. FIG. **22** shows an exemplary prosthetic device **100** having a single anchor **102**, being delivered with a catheter **104** via an exemplary transeptal atrial approach. In the approach shown in FIG. **22**, the catheter **104** passes through the inferior vena cava **110**, the right atrium **112**, and through an incision made in the septum **114**, to reach the left atrium **2**. The distal end portion **106** of the catheter **104** serves as a sheath for containing the prosthetic device **100** in a compressed state during delivery to the heart. The delivery apparatus can further include a pusher member **116** extending coaxially through the catheter **104**. Once the catheter enters the left atrium **2**, implantation of the device **100** can be performed similar to the methods described in relation to FIGS. **11-21** herein. Alternatively, the prosthetic devices described herein can be implanted via an atrial approach using any of the methods and/or devices described in U.S. Patent Application Publication No. 2011/0137397 in relation to FIGS. **63-67** thereof, or in U.S. Provisional Patent Application No. 61/760,577.

FIG. **23** shows an exemplary prosthetic device **120** having a single anchor **122**, being delivered with a delivery device **124** through the apex **126** of the heart in an exemplary transapical approach. In the transapical approach shown in FIG. **23**, the prosthetic device **120** is held in a compressed configuration in a distal end of the delivery device **124** as the delivery device is inserted through an incision in the heart apex **126** and delivered through the left ventricle **4** to the mitral region. The delivery device **124** can have features that allow the anchor **122** to radially expand out of the delivery device **124** and away from the still-compressed body of the prosthetic device **120**, as shown in FIG. **23**, to capture one of the native mitral leaflets **6** or **8**. For example, the delivery device **124** can have an outer sheath configured to release the anchor **122** while the body of the prosthetic device is held in a compressed state in an inner sheath, such as by providing a slot in the distal end portion of sheath **124** through which the anchor **122** can extend. In some embodiments, the delivery device **124** can be similar to the delivery device **2000** described in U.S. Patent Application Publication No. 2011/0137397 (for example, with only one of the slots **2028** instead of two), and can be used to implant the prosthetic device **120** via methods similar to those described therein in relation to FIGS. **49-62** thereof. The delivery device **124** can also be similar to the delivery devices described in U.S. Provisional Patent Application No. 61/760,577, and can be used to implant prosthetic devices via methods similar to those described therein.

FIG. **24** shows an exemplary prosthetic device **200** that is configured to inflate with blood and expand radially during systole and to collapse radially during diastole. The device **200** can comprise a structural portion **202**, an anchor **204**, and an inflatable portion, or parachute, **206** having an annular cross-sectional profile. The structural portion **202** can comprise a rigid member or frame that supports one side of the parachute **206**. The anchor **204** can comprise an extension of the structural member **202** or a separate member coupled to the structural member and is configured to attach the device **200** to one of the native mitral leaflets, such as the posterior native leaflet as shown in FIG. **24**, by capturing the leaflet between the anchor **204** and the structural portion **202**. The parachute **206** can comprise a flexible, blood-impermeable material, such as PET fabric or the like. The parachute **206** has an open lower end **208** and a closed upper end **210**.

During systole, as illustrated in FIG. **24**, higher pressure in the left ventricle relative to the left atrium forces blood from the left ventricle into the open lower end **208** of the parachute. The increased pressure in the parachute (labeled P_2 in FIG. **24**) exceeds the pressure in the left atrium (labeled P_1 in FIG. **24**), causing the parachute to inflate with blood and to expand radially and upwardly. At the same time, the native leaflets **6**, **8** are caused to collapse toward each other. The device **200** moves along with the leaflet to which it is attached and the other leaflet moves toward the expanding parachute **206**. When fully inflated, the parachute **206** can seal the gap between the two native mitral leaflets **6**, **8** and prevent or reduce mitral regurgitation.

During diastole (not shown), P_1 exceeds P_2 causing the parachute **206** to deflate and collapse toward the structural portion **202**. At the same time, the two native leaflets **6**, **8** are pushed apart. This allows blood to flow from the left atrium to the left ventricle with minimal obstruction by the collapsed parachute **206**.

In some embodiments, the device **200** can comprise additional structural elements. For example, some embodiments can comprise longitudinal splines that extend from the upper end **210** to the lower end **208** to provide longitudinal rigidity to the parachute without impeding expansion/contraction in the radial direction, much like a common umbrella. In some embodiments, the device **200** can comprise a structural member at the lower opening **208** to prevent the lower opening from fully closing during diastole, such that blood can more easily enter the lower opening at the beginning of systole. In some embodiments, the device **200** can comprise a biased portion that urges the lower opening **208** toward an opened position. The biased portion can comprise a spring mechanism, resiliently flexible members, or other mechanisms. In some embodiments, the device **200** can further comprise an atrial portion that extends from or adjacent to the upper end **210** and contacts the atrial walls and/or the atrial side of the leaflet to which the device is attached. The atrial body can help secure the device within the mitral orifice and can prevent movement toward the left ventricle. The atrial body can comprise a separate component or an extension of the structural member **202**. The atrial body can be configured like the atrial bodies **26**A, **26**B or **26**C described above, or can have other configurations.

FIGS. **25-28** show a prosthetic spacer **220** according to another embodiment, wherein the spacer **220** is coupled to one of the native leaflets using, for example, sutures. The spacer **220** can be formed from any of various suitable materials, including bio-compatible materials such as pericardial tissue, polymers, sponge, or a gel or saline filled structure such as a balloon. The material composition of the spacer **220** can be selected to increase desirable characteristics of the

spacer **220**, such as performance, durability, promotion of native tissue growth, etc. The spacer **220** can be formed in any of various suitable shapes, such as a rectangle, a semi-elliptical ring or generally u-shape, or a semi-ellipse. As shown in FIG. **25**, the spacer **220** can be sutured to the posterior leaflet **8** using sutures **222** via a transeptal approach, and as shown in FIG. **26**, the spacer **220** can be sutured to the posterior leaflet **8** using sutures **222** via a transapical approach. In use, the opposite leaflet (the anterior leaflet in the illustrated embodiment) can coapt against the spacer **220** to prevent or minimize regurgitation.

FIG. **27** shows the spacer **220** after it has been sutured to the native posterior leaflet **8**. As shown, two sutures **222** can be sufficient to couple the spacer **220** to the leaflet **8**. The sutures **222** can be positioned as shown, with one suture **222** at either end of the spacer **220**, which spans across the leaflet **8**. In alternative embodiments, additional or fewer sutures can be used, and the sutures can be situated in alternative locations on the spacer **220** and/or on the leaflet **8**.

FIG. **28** shows the spacer **220** being coupled to the posterior native leaflet **8** using a length of elongated material **224** and a pair of slidable locking devices **226**. The elongated material **224** can comprise, for example, a length of thread or suture material, or a metal or polymeric wire, or other material suitable for suturing, such as biological tissue. In the illustrated embodiment, a single strand of material **224** is used, although in alternative embodiments, two or more strands **224** can be used to couple the spacer **220** to the native leaflet **8**. In order to couple the spacer **220** to the native posterior leaflet **8**, one or both of the slidable locking devices **226** can be guided along the strand of material **224** toward the native leaflet **8**, thereby decreasing the length of the strand **224** between the locking devices **226** until the spacer **220** is held firmly against the leaflet **8** in a desired deployed configuration. Because the locking devices **226** are positioned behind the posterior leaflet **8** in this configuration (that is, they are located between the native leaflet **8** and the wall of the left ventricle **4**), the potential for interference between the locking devices **226** and the coaptation area of the leaflets **6**, **8** is minimized. Once the spacer **220** is situated in this configuration, any excess material **228** can be trimmed to prevent interference of the material **224** with the operation of the heart valve. The locking devices **226** can be configured to be slid or passed over a suture in one direction and resist movement in the opposite direction. Examples of locking devices (also referred to as suture securement devices) that can be implemented in the embodiment of FIG. **28** are disclosed in co-pending application Ser. No. 13/938,071, filed Jul. 9, 2013, which is incorporated herein by reference.

FIGS. **25-28** show one spacer **220** coupled or secured to the posterior leaflet **8**. In alternative embodiments, a spacer **220** can be coupled as described above to the anterior leaflet **6** in place of or in addition to the spacer **220** coupled to the posterior leaflet **8**. Except where physically impossible, any of the embodiments described herein can be sutured to native tissue as described above with reference to spacer **220**, rather than or in addition to being clipped to the native leaflets using one or more anchors.

By anchoring a prosthetic mitral device to one of the mitral leaflets, as disclosed herein, instead of anchoring the device to the walls of the left ventricle, to the walls of the left atrium, to the native valve annulus, and/or the annulus connection portions of the native leaflets, the device anchorage is made independent of the motions of the ventricular walls and atrial walls, which move significantly during contractions of the heart. This can provide a more stable anchorage for a prosthetic mitral device, and eliminate the risk of hook-type or cork screw-type anchors tearing or otherwise causing trauma to the walls of the left ventricle or left atrium. Furthermore, the device body can be held in a more consistent position with respect to the mitral leaflets as the leaflets articulate, eliminating undesirable motion imparted on the device from the contraction motions of the left ventricle walls and left atrium walls. Anchoring to a mitral leaflet can also allow for a shorter body length compared to devices having other anchorage means.

Leaflet Extension

FIG. **29** shows another exemplary prosthetic device **300** implanted at the mitral valve region for treating regurgitation. The device **300** comprises a strong, flexible sheet of blood-impermeable material. The device **300** has an upper end **302** that is secured to the mitral annulus and/or the region of a mitral valve leaflet adjacent to the mitral annulus. The portion of the device **300** extending away from this upper end portion **302** is a free end portion of the device **300**. In the illustrated example, the upper end **302** is attached to the mitral annulus above the posterior leaflet **8**. In other examples, the arrangement can be reversed with the device **300** secured to the anterior leaflet **6**. The device **300** can be secured to the native tissue by various means, such as via suturing or via barbed anchors or microanchors **304**. The upper end **302** of the device **300** can be wider than the free end portion of the device **300**, thus the device **300** can have a generally trapezoidal shape.

In FIG. **29**, the lower end of the anterior leaflet **6** is not shown in order to show the lower end of the posterior leaflet **8** and the lower end **306** of the device **300** extending downwardly through the mitral orifice and into the left ventricle **4**. The lower end **306** of the device can be shorter, longer, or about the same length as the leaflet to which it is attached. As shown in FIGS. **30** and **31**, the lower end **306** of the device in the illustrated embodiment extends below the lower end of the posterior leaflet during diastole (FIG. **31**), and extends short of the lower end of the anterior leaflet **6** during systole (FIG. **30**). The lower end **306** can be tethered to a location in the left ventricle **4**. For example, the lower end **306** can be tethered to the papillary muscle heads **310** via tethers **308** and anchors **312**, as shown, (in a manner similar to the way in which the native chordae tendineae **314** tether the native leaflet **8** to the papillary muscles **310**), or can be tethered to the apex of the left ventricle.

During systole, as shown in FIG. **30**, the device **300** inflates or fills with blood from the left ventricle **4** and expands laterally toward the anterior leaflet **6**. This causes the lower portion of the device **300** to seal against the anterior leaflet **6**, blocking the flow of blood back into the left atrium **2**. The lateral edges of the device **300** can seal between the two native leaflets adjacent to the commissures where the native leaflets still naturally coapt with each other. The tethers **308** prevent the lower end **306** of the device **300** from moving toward and/or into the left atrium **2** and thereby breaking the seal with the anterior leaflet **6**. Thus, the device **300** augments the native posterior leaflet and helps seal the mitral orifice in the case where the native leaflets **6**, **8** do not otherwise not fully coapt and allow regurgitation between them.

During diastole, as shown in FIG. **31**, high pressure in the left atrium **2** forces the device **300** to collapse against the posterior leaflet **8**, allowing blood to flow into the left ventricle **4** with minimal obstruction from the device **300**.

FIG. **32** shows another exemplary prosthetic device **400** implanted at the mitral valve region for treating mitral regurgitation. The device **400** comprises a rigid frame **402** (e.g., a metal frame) that clips around the posterior leaflet **8** with an anchor portion **404** being positioned behind the posterior

leaflet **8** and an atrial portion **406** being positioned along the atrial surface of the mitral annulus and/or the portion of the posterior leaflet adjacent to the annulus. The frame **402** can secure the device **400** to the posterior leaflet **8** without sutures or other tissue puncturing elements like the anchors **304** in FIGS. **29-31**. The device **400** also can be implanted on the anterior leaflet **6**. The device **400** further comprises a strong, flexible sheet **408** of blood-impermeable material, like the device **300**. An upper end **410** of the sheet **408** can be secured to the frame **402** at or near the atrial portion **406**. The portion of the sheet **408** extending away from this upper end portion **410** is a free end portion of the sheet **408**.

In FIG. **32**, the lower end of the anterior leaflet **6** is not shown in order to show the lower end of the posterior leaflet **8** and the lower portions of the device **400** extending downwardly through the mitral orifice and into the left ventricle **4**. The lower end **412** of the sheet **408** can be shorter, longer, or about the same length as the lower end of the leaflet to which it is attached. As shown in FIGS. **33** and **34**, the lower end **412** of the sheet **408** in the illustrated embodiment extends below the lower end of the posterior leaflet during diastole (FIG. **34**), and extends short of the lower end of the anterior leaflet **6** during systole (FIG. **33**). The lower end **412** can be tethered to a location in the left ventricle **4** and/or can be tethered to one or more points **420** near the lower end of the frame **402** (both tethering means are shown in FIGS. **33** and **34**, though one can be used without the other). For example, in some embodiments, the lower end **412** of the sheet **408** can be tethered to the papillary muscle heads **416** via tethers **424** and anchors **426** (in a manner similar to the way in which the native chordae tendineae **414** tether the native leaflet **8** to the papillary muscles **416**), and/or can be tethered to the apex of the left ventricle **4**. In other embodiments, the sheet **408** is tethered only to the frame **402** and tethers extending down into the left ventricle **4** are optional. In such embodiments, one or more tethers **428** can extend from adjacent the lower end **412** of the sheet, such as from the lower lateral corners **422**, and attach to the lower end of the frame at or near points **420**. In some embodiments, the sheet **408** can adopt a three dimensional curvature when inflated, with the lower corners being held closer to the lower end of the frame **402** while an intermediate portion of the lower edge **412** is allowed to billow out (somewhat like a spinnaker sail) further toward the anterior leaflet **6** to create a seal.

During systole, as shown in FIG. **33**, the sheet **408** inflates or fills with blood from the left ventricle **4** and expands laterally toward the anterior leaflet **6**. This causes the lower portion of the sheet **408** to seal against the anterior leaflet **6**, blocking the flow of blood back into the left atrium **2**. The lateral edges of the sheet **408** can seal between the two native leaflets adjacent to the commissures where the native leaflets naturally coapt with each other. Thus, the device **400** augments the native posterior leaflet and helps seal the mitral orifice in the case where the native leaflets **6**, **8** do not otherwise not fully coapt and allow regurgitation between them.

During diastole, as shown in FIG. **34**, high pressure in the left atrium **2** forces the sheet **408** to collapse against the posterior leaflet **8**, allowing blood to flow into the left ventricle **4** with minimal obstruction from the device **400**.

FIGS. **35** and **36** show embodiments of prosthetic devices **460**, **470** which can be used to extend the effective length of the native leaflets **6**, **8**. As shown in FIG. **35**, a prosthetic device **460** can include a body **462** and a clip **464** for clipping the device **460** to one of the anterior or posterior native leaflets **6**, **8**. As shown in FIG. **36**, a prosthetic device **470** can include a body **472** and one or more sutures **474** for coupling the device **470** to one of the anterior or posterior native leaflets **6**, **8**. In use, the devices **460**, **470** have free end portions extending away from the native leaflets which extend the effective length of the native leaflets, thereby increasing the chance of and extent of coaptation between them, as described more fully below. The bodies **462**, **472** can comprise a material which is stiff enough to reduce the chance of leaflet prolapse, and flexible enough to increase the extent of leaflet coaptation. Suitable materials can include, for example, biological materials such as pericardial tissue, goretex, silicone, polyurethane, or other polymeric materials. FIG. **35** shows that a device **460** can be used on each of the anterior and posterior native leaflets **6**, **8**, and FIG. **36** shows that a device **470** can be used on each of the anterior and posterior native leaflets **6**, **8**, but in alternative embodiments, only one such device can be used, or one device **460** and one device **470** can be used. FIG. **35** shows that tethers **461** can be used to tether free end portions of the bodies **462** to locations in the left ventricle, thus reducing the chances of prolapse of the prosthetic devices **460** during systole. The tethers **461** are optional, and can be used in a similar fashion in combination with the devices **470**, **500**, **502**, or any other suitable devices described herein.

FIG. **37** shows exemplary prosthetic devices **500**, **502** which combine features of the prosthetic spacers and the leaflet extensions described above. Prosthetic device **500** is shown coupled to the posterior native leaflet **8** while the prosthetic device **502** is shown coupled to the anterior native leaflet **6**. The prosthetic devices **500**, **502** include relatively thick upper portions **504**, **506**, which function in a manner similar to the prosthetic spacers described above, and relatively thin, elongate free end portions **508**, **510**, which function in a manner similar to the devices **300**, **400**, described above. The free end portions **508**, **510** can have respective distal end portions **514**, **516**, which represent the effective distal ends of the extended leaflets.

In use, the free end portions **508**, **510** extend the effective length of the respective leaflets, and can facilitate initiation of leaflet coaptation during ventricular systole. During systole, the leaflets are urged toward one another due to the pressures extant in the left ventricle and left atrium. Due to the extended effective length of the leaflets, the end portions **514**, **516** are more likely to coapt than were the ends of the native leaflets without the extensions. Once coaptation is initiated, and thus blood flow from the left ventricle to the left atrium at least partially impeded, the pressure in the left ventricle can increase, further increasing the pressure differential between the left ventricle and the left atrium and urging the leaflets **6**, **8**, further toward one another.

As a result, the portions of the leaflets **6**, **8**, and their respective extensions **502**, **500** which coapt, increases (both in the direction from the end portions **514**, **516** toward the left atrium **2**, and from the locations of the devices **500**, **502**, toward the commissure points of the mitral valve), leading to a cycle of increasingly impeded blood flow, increased pressure differential, and increased coaptation of the leaflets. Thus, by facilitating initiation of coaptation, the free end portions **508**, **510** can help to reduce regurgitation of blood from the left ventricle to the left atrium during ventricular systole. Further, the upper portions **504**, **506** can further help to prevent regurgitation in the manner described above with respect to prosthetic device **10**. In cases where the native leaflets **6**, **8**, do not experience sufficient coaptation to prevent regurgitation, the relatively thick upper portions **504**, **506**, can help to increase their coaptation and thereby reduce regurgitation.

FIG. **37** shows that the devices **500**, **502** can be sutured to the native leaflets **8**, **6**, with sutures **512**, but in alternative

embodiments, the devices **500**, **502** can be clipped to the native leaflets **8**, **6**, as described above. In alternative embodiments, only one of the devices **500**, **502** can be used rather than both.

Spacers Having Plural Anchors

In some embodiments, prosthetic devices can include a body and a plurality of anchors such that the body can be clipped to more than one leaflet. Such embodiments can be used to effectively couple two or more leaflets to one another. Thus, such a device can be used to bring native leaflets closer to one another and restrict their mobility in order help increase the chance of or extent of coaptation between the leaflets.

FIGS. **38-41** show a prosthetic spacer **600** having a body **602**, a first anchor **604** and a second anchor **606**. The body **602** and anchors **604**, **606** can be fabricated from any of various suitable materials, and the body is desirably made from a relatively compressible material so that its profile can be reduced for delivery into a patient's heart within a delivery catheter. Alternatively, the body **602** can be inflatable (e.g., to be inflated with a fluid such as saline or a curing epoxy or polymer) or otherwise expandable (e.g., it can be fabricated from a frame comprising a self-expanding material such as Nitinol) such that the cross section of the body **602** can be reduced for delivery into a patient's heart and then expanded to a final, deployed configuration therein. An inflatable spacer can be particularly advantageous because it can allow enhanced customization of the spacer, and can allow fine control over the final, deployed size and configuration of the spacer.

FIGS. **38** and **39** show that the anchors can have similar structures. Each anchor **604**, **606** can be made from a single piece of relatively rigid metallic material (e.g., an elongated wire) which can include first and second inner portions **608**, **610**, first and second bottom portions **612**, **614**, and a main loop portion **616** extending between and connecting the upper ends of the bottom portions **612**, **614**. The inner portions **608**, **610** can be coupled rigidly to the inside of the body **602**. The inner portions **608**, **610** can extend downwardly out of the lower end of body **602** to the respective bottom portions **612**, **614**, which can each curve upwardly around the lower end of the body **602** to meet the main loop portion **616**.

FIGS. **39** and **40** show that the structure of the anchors **604**, **606**, and their connections to the body **602**, biases the main loop portions **616** of the anchors **604**, **606**, into contact with the sides of the body **602**. Thus, in use, the spacer **600** can be clipped to the anterior and posterior native leaflets **6**, **8**, with one of the leaflets **6**, **8** clipped between the anchor **604** and the body **602**, and the other of the leaflets **6**, **8**, clipped between the anchor **606** and the body **602**. FIG. **41** shows that the anchors **604**, **606** can be splayed apart so that gaps exist between the anchors **604**, **606**, and the body **602**. Thus, the spacer **600** can be introduced into the region of a patient's native mitral valve in a closed configuration with the anchors **604**, **606** against the side of the body **602** (FIGS. **38-40**). The anchors **604**, **606** can then be splayed apart or expanded into an open configuration (FIG. **41**) so the spacer can be positioned with the native leaflets **6**, **8**, in the gaps between the anchors **604**, **606** and the body **602**, after which the anchors **604**, **606** can be allowed to return to the closed configuration under their own resiliency to capture the leaflets **6**, **8**, and clip the spacer **600** thereto.

FIG. **42** shows that in use, the prosthetic spacer **600** can be clipped to the posterior native mitral valve leaflet **8** using the first anchor **604**, as described above with regard to prosthetic spacer **10** and shown in FIG. **1**, and can be clipped to the anterior native mitral valve leaflet **6** using the second anchor **606**, as described above with regard to prosthetic spacer **10** and shown in FIG. **2**. FIG. **43** shows that when the prosthetic spacer **600** is clipped to both of the leaflets **6**, **8**, (e.g., at the A2 and P2 regions of the leaflets, as identified by Carpentier nomenclature) it brings them together, decreasing the overall area of the mitral valve orifice, and dividing the mitral valve orifice into two orifices **618**, **620** during diastole. Thus, the area through which mitral regurgitation can occur is reduced, leaflet coaptation can be initiated at the location of the spacer **600**, and the leaflets can fully coapt more easily, thereby preventing or minimizing mitral regurgitation.

FIGS. **44** and **45** show alternative embodiments of dual anchor spacers clipped to the A2 and P2 regions of the anterior and posterior native leaflets **6**, **8**, as viewed from the left atrium. FIG. **44** shows an embodiment **640** in which the shape of the body of the spacer **640** is relatively elongate such that the spacer **640** extends substantially between the commissures **650**, **652** of the mitral valve. As shown, in this embodiment, the native leaflets **6**, **8** are brought toward one another by the anchors of the spacer **640**, the overall area of the valve orifice is reduced, and the orifice is divided into four orifices **642**, **644**, **646**, **648** during diastole. Thus, the area through which mitral regurgitation can occur is reduced, leaflet coaptation can be initiated at the location of the spacer **640**, and the leaflets can fully coapt more easily, thereby preventing or minimizing mitral regurgitation. In addition, the shape of the spacer **640** can more effectively treat eccentric jet mitral regurgitation, because the extension of the body of the spacer **640** to the commissures **650**, **652** helps the leaflets **6**, **8**, to coapt across the entirety of the native mitral valve orifice.

FIG. **45** shows an embodiment of a dual-anchor spacer **660** in which the body of the spacer **660** comprises a prosthetic valve having one or more flexible leaflets **666** that permit blood to flow into the left ventricle during diastole and block the back flow of blood into the left atrium during systole. In this embodiment, the native leaflets **6**, **8** are brought closer to one another and the native mitral valve orifice is divided into two orifices **662**, **664** during diastole. Because the body of the spacer **660** comprises a prosthetic valve, rather than a solid piece of material, the total effective open area between the leaflets during diastole (e.g., the area through which blood can flow) is greater in this embodiment than in the embodiment illustrated in FIGS. **43** and **44**.

In alternative embodiments, the body of a dual anchor spacer can have various alternative shapes. For example, cross-sectional profile of the body can be circular, elliptical, or as shown in FIG. **46**, can have a generally crescent shape. A spacer body having a crescent shape such as spacer body **680** in FIG. **46** (viewed from the left atrium) can be particularly advantageous because it can conform to the overall crescent shape of the anterior and posterior leaflets **6**, **8** of the native mitral valve. In such an embodiment, the concave side **682** of the crescent shaped body **680** can face the anterior native leaflet **6** while the convex side **684** of the crescent shaped body **680** can face the posterior native leaflet **8**. FIG. **46** shows that in such an embodiment, the native mitral valve orifice can be divided into two orifices **686**, **688**, each on the concave side **682** of the spacer **680**, as the convex side **684** can conform to the posterior native leaflet **8** such that no openings exist between them.

FIGS. **47-51** show embodiments of spacers having three anchors, which can be clipped to leaflets in the tricuspid valve of the human heart in a manner similar to that described above with regard to spacers in the mitral valve. FIG. **47** shows a tricuspid spacer **700** having a circular body **712** and three anchors **702**. FIG. **48** shows the spacer **700** implanted in the tricuspid valve (as viewed from the right ventricle, as blood is

being pumped out of the right ventricle), with each of the three anchors **702** clipped to a respective leaflet **704** of the tricuspid valve, and thereby coupling them to one another. FIG. **49** shows the spacer **700** clipped to the leaflets **704** of the tricuspid valve as blood is pumped from the right atrium to the right ventricle through orifices **706**, **708**, **710**. FIG. **50** shows an alternative tricuspid spacer **720** having a body **722** and three clips **724**. As shown, the body **722** can have a generally Y shape. FIG. **51** shows an alternative tricuspid spacer **730** having a body **732** and three clips **734**. As shown, the body **732** can have a generally triangular shape.

FIGS. **52-54** show an exemplary dual anchor spacer **750** having a body **752** and first and second anchors **754**, **756**, positioned within a native mitral valve. FIG. **52** shows the spacer **750** as seen from the left ventricle **4**. FIG. **53** shows the spacer **750** as viewed from the left atrium **2** during systole, and FIG. **54** shows the spacer **750** from the left atrium **2** during diastole. As can be seen in FIG. **53**, no openings appear through which regurgitant flow can occur. As can be seen in FIG. **54**, two openings **758**, **760** exist through which blood can flow from the left atrium **2** to the left ventricle **4** during diastole, as is desirable.

A suitable delivery sequence for delivering a prosthetic spacer such as spacer **750** to the mitral valve region of a patient's heart can comprise compressing a spacer to a compressed, delivery configuration, delivering the spacer to the coaptation line of a patient's native mitral valve, expanding the spacer until regurgitation in the patient's mitral valve is adequately reduced (an inflatable device can allow a physician to make fine adjustments to the final size and configuration of the spacer based on information received during the delivery process), manipulating the anchors of the spacer to an open position, capturing the native leaflets between the anchors and the body of the spacer, and then manipulating the anchors to a closed position, thereby clipping the spacer to the native mitral valve leaflets.

FIGS. **55** and **56** show an exemplary dual anchor spacer **800** comprising a main body **802** and first and second anchors **804**, **806**. The main body **802** can comprise a plurality of interconnected struts **808** which together form a plurality of open cells and are arranged to form a generally annular shape having first and second end portions **816**, **818**. The body **802** can be formed to be radially self-expandable. For example, the body **802** can be fabricated from a shape-memory material such as Nitinol, which can allow the spacer **800** to be radially compressed to a compressed delivery configuration, delivered to one of a patient's native heart valves, then self-expanded to an expanded functional configuration for use within the patient's heart.

The first anchor **804** can comprise first and second end portions **810**, **812** which can be coupled to the first end portion **816** of the main body **802**, and a loop portion **814** which can extend between the first and second end portions **810**, **812**. The first and second end portions **810**, **812** can extend away from the first end portion **816** of the body **802**, then curl back and extend toward the second end portion **818** of the main body **802**. The loop portion **814** can be coupled to the first end portion **810**, extend generally toward the second end portion **818** of the main body **802**, curl back and extend toward the first end portion **816** of the main body **802**, and be coupled to the second end portion **812**.

Thus, the first anchor **804** can be coupled to the first end portion **816** of the main body **802** and extend along the side of the main body **802** toward its second end portion **818**. The second anchor **806** can have a similar structure, and can be coupled to the main body **802** such that it extends along an opposing side of the main body **802**. In this embodiment, the spacer **800** can be clipped to native tissues by pinching the native tissues between the anchors **804**, **806** and the respective sides of the main body **802**. The anchors **804**, **806** can be made from various suitable materials, and in one exemplary embodiment can be fabricated from the shape-memory material Nitinol. The anchors **804**, **806** in the illustrated embodiment are fabricated from separate pieces of material from the main body **802**, and are coupled to the main body **802** using coupling mechanisms **820**. The coupling mechanisms **820** can be, for example, crimping rings that extend around a strut at the first end **816** of the main body **802** and an adjacent portion of an anchor. In alternative embodiments, however, the anchors **804**, **806** and the main body **802** can be fabricated integrally with one another (i.e., from a single piece of material). As best shown in FIG. **56**, the main body **802** can have a generally elliptical or oval shape when viewed on end, but in alternative embodiments, the main body can be formed to have any of various suitable shapes when viewed on end, such as a circle.

FIGS. **57** and **58** show the spacer **800** covered in a blood impermeable fabric material **822**, such as made of polyethylene terephthalate (PET) or polyurethane. The fabric material **822** can be relatively thick, strong, and soft, such as a knitted lofty cloth. The fabric material **822** can be selected to provide a softer surface for contact with the native tissue, thus reducing trauma caused to the native tissues by the implantation of the spacer **800**, can be selected to promote native tissue ingrowth into the spacer **800**, and/or can be selected to improve the seal formed between native tissues and the portions of the spacer **800** they come into contact with. Additionally, FIG. **58** shows that a fabric layer **824** can be disposed to cover all or substantially all of the opening at the center of the main body **802**. The layer **824** can be blood impermeable, thereby blocking the flow of blood through the spacer **800**. The layer **824** can be formed from the same material as fabric **822**, and together the fabric **822** and layer **824** can work to prevent the regurgitant flow of blood through a heart valve when the spacer has been implanted therein.

FIGS. **59-63** illustrate exemplary systems and methods which can be used to implant the spacer **800** in a native heart valve. FIGS. **59-61** illustrate exemplary systems and steps which can be used to crimp the spacer **800** to a compressed, delivery configuration, suitable for delivery to a patient's native heart valve within a delivery device **850**. FIG. **59** shows the spacer **800** with its main body **802** positioned in a crimper mechanism **900** capable of crimping the main body **802** to a compressed configuration. As shown, the anchors **804**, **806** can remain outside the crimper mechanism **900** as it is used to crimp the main body portion **802**. For example, U.S. Pat. No. 7,530,253, which is hereby incorporated herein by reference, describes an exemplary prosthetic valve crimping device that can be used to crimp the spacer **800**.

In some embodiments, the delivery device **850** can be similar to the delivery device **2000** described in U.S. Patent Application Publication No. 2011/0137397 or the delivery devices described in U.S. Provisional Patent Application No. 61/760,577, and can be used to implant prosthetic devices via methods similar to those described therein. FIG. **59** shows that the delivery device **850** can include an inner sheath **852** provided with a pair of slots **854** disposed on opposing sides of the inner sheath **852**, and an internal locking element **856**, which is axially adjustable relative to the inner sheath **852** along a central longitudinal axis of the inner sheath **852**. The internal locking element **856** can comprise a generally cruciform shape, having four extension portions **858** between which are defined four voids **860**. As best shown in FIG. **59**, two of the voids **860** can be aligned with the two slots **854**,

which can also be aligned with the portions of the anchors **804**, **806** which are coupled to the body **802** of the spacer **800**. Thus, in this embodiment, the locking element **856** can be retracted into the inner sheath **852**, thereby pulling the main body portion **802** of the spacer **800** into the inner sheath **852** in the same direction. As best shown in FIG. **60**, as the spacer **800** is pulled into the inner sheath **852**, the first and second end portions **810**, **812** of each of the anchors extend from the first end portion **816** of the spacer **800**, through the respective voids **860** in the locking element, and then curl out of the slots **854** in the sides of the inner sheath **852**, extending along the sides of the body **802** toward the second end portion **818** of the main body **802**. In this way, the body **802** of the spacer **800** can be pulled into the inner sheath **852** and thereby compressed to a compressed delivery configuration.

As shown in FIG. **61**, after the main body portion **802** has been situated within the inner sheath **852**, an outer sheath **862** can be extended toward the distal end of the device **850** so as to enclose the anchors **804**, **806**, thereby causing them to wrap around the inner sheath **852** and be confined between the inner sheath **852** and outer sheath **862**.

FIGS. **62** and **63** show a spacer **800** covered in fabric as described above and situated within a delivery device **870** in two different configurations. FIG. **62** shows the spacer **800** having its main body portion **802** situated within an inner sheath **872** of the delivery device **870** such that the anchors **804**, **806** extend toward a distal end portion of the delivery device **870**. In this embodiment, an outer sheath **874** can be extended distally to retain and secure the anchors **804**, **806** against the sides of the inner sheath **872**. Such a configuration can be used to deliver the spacer transapically, as described below. In some embodiments, retraction of the outer sheath **874** can allow the anchors **804**, **806** to self-expand to a splayed-apart configuration.

FIG. **62** also shows that forcible expanders, or levers, **876** can be used to force the anchors **804**, **806** to splay apart. The forcible expanders **876** can be radially self-expanding levers which radially self-expand when the outer sheath **874** is retracted or are otherwise configured to radially expand away from the inner sheath when they are actuated by a physician (such as by actuating a control knob on a handle that is operatively connected to the expanders **876**). The expanders **876** can alternatively be sutures or other mechanisms which can be actuated by a physician to force the anchors **804**, **806** to splay apart. In some embodiments, retraction of the outer sheath **874** can allow the anchors **804**, **806** to self-expand to a first splayed-apart configuration, and forcible expanders **876** can be actuated to force the anchors **804**, **806** to further radially expand to a second splayed-apart configuration. In such an embodiment, the expanders **876** can be actuated to cause the anchors **804**, **806** to radially expand to the second splayed apart configuration, and can then be actuated to allow the anchors **804**, **806** to move radially inward and return to the first splayed-apart configuration.

FIGS. **62** and **63** illustrate the spacer **800** situated within the delivery system **870** such that the anchors **804**, **806** extend generally along the outside of the body **802** toward the second end portion **818** of the spacer **800**. In alternative embodiments, however, the configuration of the body **802** and anchors **804**, **806** within the delivery system **870**, and the deployment of the spacer **800** from the delivery system **870**, can be similar to that illustrated in FIGS. **12-15** with respect to device **50** and delivery catheter **56**.

FIG. **63** shows the spacer **800** having its main body portion **802** situated within the inner sheath **872** of the delivery device **870** such that the anchors **804**, **806** extend toward a proximal end portion of the delivery device **870**. In this embodiment, the outer sheath **874** can be extended distally to retain and secure the anchors **804**, **806** against the sides of the inner sheath **872**. Such a configuration can be used to deliver the spacer transatrially, as described below.

Prosthetic spacers described herein can be delivered using minimally invasive approaches. FIGS. **64-67** show various approaches by which a prosthetic spacer **800** can be delivered to the region of a patient's mitral valve using a delivery system **920**. For example, a prosthetic spacer can be delivered via a transapical approach (FIG. **64**), via a transeptal approach (FIG. **65**), via a transatrial approach (FIG. **66**), or via a transfemoral approach (FIG. **67**). FIGS. **64-67** show that the delivery system **920** can comprise an outer sheath **922**, an inner sheath **924**, and a guidewire **930** which can extend through the outer sheath **922** and inner sheath **924**. The delivery system **920** can also include a pusher element (not illustrated in FIGS. **64-67**, but similar to those described above), which can be actuated to move the spacer **800** within the inner sheath **924**. The outer sheath **922**, inner sheath **924**, guidewire **930**, and pusher element can each be retracted proximally or extended distally with respect to one another. The guidewire **930** can be used to guide the delivery of the other components of the system **920** to an appropriate location within a patient's vasculature. The guidewire **930** can extend through a small opening or pore in the spacer **800**, for example in the fabric layer **824**, the small opening or pore being small enough that substantial blood cannot flow therethrough.

FIGS. **64** and **67** show that the deployment of the spacer **800** to a native mitral valve via the transapical approach can be similar to the deployment of the valve **800** via the transfemoral approach, at least because in both cases the valve is delivered to the mitral valve from the left ventricle. In preparing the delivery system **920** for delivery of the spacer **800** via the transapical or the transfemoral approach, the spacer **800** can be situated within the system **920** with the second end portion **818** of the spacer **800** disposed at the distal end of the system **920** (such as shown in FIG. **62**). In the transapical and the transfemoral approaches, the delivery system **920** can be used to first deliver the spacer **800** to the region of the native mitral valve from the left ventricle. In the transapical approach, the delivery device **920** is inserted into the left ventricle via an opening in the chest and the apex of the heart. In the transfemoral approach, the delivery device **920** can be inserted into a femoral artery and advanced through the aorta in a retrograde direction until the distal end of the delivery device is in the left ventricle. The outer sheath **922** can then be retracted proximally such that the anchors **804**, **806** are no longer confined within the outer sheath **922**. In some embodiments, the anchors **804**, **806** can be configured to self-expand to a splayed apart configuration shown in FIGS. **64** and **67**. In other embodiments, as described above, the delivery system **920** can include a mechanism for forcing the anchors **804**, **806** to splay apart to the splayed-apart configuration (such as described above with respect to the embodiment of FIG. **62**).

The device **920** can then be distally advanced so that the native mitral valve leaflets are positioned between the splayed apart anchors **804**, **806**, and the body **802**. The inner sheath **924** can then be retracted so that the body **802** is no longer confined within the inner sheath **924** and can radially expand to an expanded configuration between the native mitral valve leaflets. In some embodiments, the body **802** can expand such that the native leaflets are pinched between the body **802** and the anchors **804**, **806**. In alternative embodiments, as described above, the mechanism for forcing the anchors **804**, **806** to splay apart can be actuated to allow the anchors **804**, **806** to move radially inward toward the main body **802**,

thereby pinching the native leaflets between the main body **802** and the anchors **804**, **806**.

FIGS. **65** and **66** show that the deployment of the spacer **800** to a native mitral valve via the transseptal approach can be similar to the deployment of the valve **800** via the transatrial approach, at least because in both cases the valve is delivered to the mitral valve from the left atrium. In preparing the delivery system **920** for delivery of the spacer **800** via the transseptal or the transatrial approach, the spacer **800** can be situated within the system **920** with the first end portion **816** of the spacer **800** disposed at the distal end of the system **920** (such as shown in FIG. **63**). In these approaches, the delivery system **920** can be used to first deliver the spacer **800** to the region of the native mitral valve from the left atrium. The outer sheath **922** can then be retracted proximally such that the anchors **804**, **806** are no longer confined within the outer sheath **922**. In some embodiments, the anchors **804**, **806** can be configured to self-expand to a splayed apart configuration shown in FIGS. **65** and **66**. In other embodiments, as described above, the delivery system **920** can include a mechanism for forcing the anchors **804**, **806** to splay apart to the splayed-apart configuration.

The system **920** can then be proximally retracted so that the native mitral valve leaflets are positioned between the splayed apart anchors **804**, **806**, and the body **802**. The inner sheath **924** can then be retracted so that the body **802** is no longer confined within the inner sheath **924** and can radially expand to an expanded configuration between the native mitral valve leaflets. In some embodiments, the body **802** can expand such that the native leaflets are pinched between the body **802** and the anchors **804**, **806**. In alternative embodiments, as described above, the mechanism for forcing the anchors **804**, **806** to splay apart can be actuated to allow the anchors **804**, **806** to move radially inward toward the main body **802**, thereby pinching the native leaflets between the main body **802** and the anchors **804**, **806**.

In any of the four approaches described above, once the native leaflets have been captured by the spacer **800**, the delivery system **920** can be retracted and removed from the patient's vasculature. The spacer **800** can remain in the native mitral valve region, with the main body **802** being situated between the two native leaflets, thereby helping to reduce or prevent mitral regurgitation. It will be understood that similar techniques can be used to deliver a spacer to the native aortic, tricuspid, or pulmonary valves, depending on the needs of the patient.

In any of the four approaches described above, a marker catheter or other similar device can be used to help coordinate delivery and ensure that a desirable delivery position is achieved. An exemplary suitable marker catheter can include a standard catheter designed for angiograms, for example, a catheter made of a relatively low-density plastic material having relatively high-density metal marker bands (e.g., radiopaque marker bands) disposed at regular intervals thereon. Thus, the device can be introduced into a patient's vasculature and can be viewed under echocardiography or fluoroscopy. Alternatively, a marker wire can be used in place of the marker catheter. Another suitable alternative technique is left atrium angiography, which can help a physician visualize components of a patient's heart.

A marker catheter or marker wire can be introduced into a patient's vasculature and advanced to specific areas of the vasculature near a patient's heart. For example, a marker catheter can be advanced from a patient's jugular or femoral vein into the right atrium, then into the patient's coronary sinus. As another example, a marker catheter can be advanced from a patient's femoral artery to the patient's circumflex artery. As another example, a marker catheter can be advanced into a patient's left atrium. Once situated in the coronary sinus, circumflex artery, left atrium, or other suitable area of a patient's vasculature, the marker catheter can be used to aid a physician in delivering and ensuring desirable implantation of a prosthetic device. For example, the coronary sinus extends around the heart near the location and elevation of the mitral valve and thus can help a physician to properly size and position a prosthetic device for implantation.

For example, the patient's vasculature can be viewed under echocardiography, fluoroscopy, or other visualization technique which allows a physician to view the prosthetic device being delivered and the marker catheter. A physician can first view the devices along an axis extending from the patient's left atrium to the patient's left ventricle (referred to as a "short axis"). By viewing the devices along the short axis, a physician can deploy (such as by inflating a balloon on which an implantable device is mounted) an implantable prosthetic device and expand portions of the device to desired sizes and/or configurations based on the size and location of the marker catheter, which can provide an estimate of the size of features of the native mitral valve. Alternatively or additionally, a physician can use the marker catheter to obtain an estimate of the size of a patient's native heart valve, from which estimate a prosthetic device to be implanted in the patient's native heart valve can be selected from a set of devices having differing sizes, e.g., a set of devices having differing diameters.

A physician can also view the devices along an axis perpendicular to the short axis (referred to as a "long axis"). The long axis can have several orientations, such as from commissure to commissure, but in one specific embodiment, the long axis is oriented from the A**2** location to the P**2** location of the native mitral valve. By viewing the devices along the long axis, a physician can align an implantable prosthetic device relative to the marker catheter at a desirable location along the short axis, such that an atrial anchor of the implantable device is situated in the left atrium (above the marker catheter) and a ventricular anchor of the implantable device is situated in the left ventricle (below the marker catheter).

FIG. **68** shows an exemplary dual anchor spacer **950** which can be delivered to the region of the native mitral valve via any suitable delivery method, for example, using the transapical, transeptal, transatrial, or transfemoral techniques described above. The spacer **950** can include a main body **952**, a first anchor **954**, a second anchor **956**, and a nosecone **958**. The spacer **950** can also include a tapered portion **962**, which can couple the main body portion **952** to a neck portion **964**. The taperer portion **962** can have a variable width which can taper from the width of the main body **952** to the width of the neck portion **964**. The neck portion **964** can be configured to receive a portion of the nosecone **958** therein, and can be coupled to the nosecone **958**. The main body **952** and anchors **954**, **956** can be fabricated from various materials, as described above with regard to other embodiments, and the nosecone **958** can be fabricated from various suitable materials such as a long term implantable silicone or other suitable elastomers.

The nosecone **958** can have a small pore, or opening, or slit, **966**, which can extend through and along the length of the nosecone **958**. In accordance with suitable delivery methods making use of a guidewire such as guidewire **930**, the guidewire can extend through the opening **966**, thus eliminating the need for an opening or pore in a fabric layer. The spacer **950** can facilitate crossing of a native heart valve due to its tapered tip, which can also provide improvements in

hydrodynamics during diastolic blood flow. When a guidewire is removed from the opening **966**, the opening can close under its own resiliency and/or blood pressure, thus leaving a sealed spacer implanted at a native heart valve. Alternatively, or in addition, the opening **966** can be sufficiently small to prevent significant amounts of blood from travelling through the nosecone **958**.

The multi-anchor spacers described herein offer several advantages over previous techniques for treating regurgitation in heart valves. For example, the multi-anchor spacers described herein can be used to treat patients whose native leaflets fail to coapt at all, whereas many previous techniques required some amount of native coaptation to be efficacious. Additionally, the spacers described herein (e.g., spacer **640**) can treat eccentric jet regurgitation more readily than other known techniques. While embodiments have been illustrated with two and three anchors, the techniques described herein are generally application to spacers having any number of anchors.

General Considerations

For purposes of this description, certain aspects, advantages, and novel features of the embodiments of this disclosure are described herein. The disclosed methods, apparatuses, and systems should not be construed as limiting in any way. Instead, the present disclosure is directed toward all novel and nonobvious features and aspects of the various disclosed embodiments, alone and in various combinations and sub-combinations with one another. The methods, apparatuses, and systems are not limited to any specific aspect or feature or combination thereof, nor do the disclosed embodiments require that any one or more specific advantages be present or problems be solved.

Although the operations of some of the disclosed methods are described in a particular, sequential order for convenient presentation, it should be understood that this manner of description encompasses rearrangement, unless a particular ordering is required by specific language. For example, operations described sequentially may in some cases be rearranged or performed concurrently. Moreover, for the sake of simplicity, the attached figures may not show the various ways in which the disclosed methods can be used in conjunction with other methods. As used herein, the terms "a", "an" and "at least one" encompass one or more of the specified element. That is, if two of a particular element are present, one of these elements is also present and thus "an" element is present. The terms "a plurality of" and "plural" mean two or more of the specified element.

As used herein, the term "and/or" used between the last two of a list of elements means any one or more of the listed elements. For example, the phrase "A, B, and/or C" means "A," "B," "C," "A and B," "A and C," "B and C" or "A, B and C."

As used herein, the term "coupled" generally means physically coupled or linked and does not exclude the presence of intermediate elements between the coupled items absent specific contrary language.

In view of the many possible embodiments to which the principles disclosed herein may be applied, it should be recognized that the illustrated embodiments are only preferred examples and should not be taken as limiting the scope of the disclosure. Rather, the scope is defined by the following claims. We therefore claim all that comes within the scope and spirit of these claims.

We claim:

1. A method of implanting a prosthetic sealing device at a native mitral valve of a heart, the method comprising: advancing a delivery catheter to a native mitral valve region of a heart from a left atrium of the heart, the delivery catheter housing the prosthetic sealing device in a radially compressed configuration; advancing the prosthetic sealing device distally relative to the delivery catheter such that an anchor of the prosthetic sealing device moves out of the catheter and forms a leaflet-receiving gap between an end portion of the anchor and the delivery catheter; positioning either a posterior or an anterior mitral valve leaflet in the gap; and advancing a radially compressed body of the prosthetic sealing device out of the delivery catheter such that the body self-expands radially toward the end portion of the anchor, reducing the gap, and capturing the leaflet between the body and the end portion of the anchor, wherein the body is configured to prevent the flow of blood through the body during systole and during diastole; wherein a non-captured one of the anterior and posterior leaflets is not secured to the prosthetic sealing device when the prosthetic sealing device is implanted for intended use at the native mitral valve.

2. The method of claim **1**, wherein advancing a delivery catheter through the native mitral valve from a left atrium comprises advancing the delivery catheter through an incision in a portion of a septum between the left atrium and a right atrium.

3. The method of claim **1**, wherein when the delivery catheter is advanced to the native mitral valve region of the heart, the anchor is held in a substantially straightened position within the delivery catheter extending distally from body of the prosthetic sealing device.

4. A method of implanting a prosthetic sealing device at a native mitral valve, the method comprising: advancing a delivery device to a native mitral valve region via a left ventricle, the delivery catheter housing the prosthetic sealing device in a compressed configuration; allowing an anchor of the prosthetic sealing device to move radially out of the delivery device while a body of the prosthetic sealing device is in a compressed configuration, such that a leaflet-receiving gap forms between an end portion of the anchor and the delivery device; positioning either a posterior or an anterior mitral valve leaflet in the gap; and allowing the body of the prosthetic sealing device to radially self-expand such that the leaflet is captured between the body and the anchor, wherein the body is configured to prevent the flow of blood through the body during systole and during diastole; wherein a non-captured one of the anterior and posterior mitral valve leaflets is not secured to the prosthetic sealing device when the prosthetic sealing device is implanted for intended use at the native mitral valve.

5. The method of claim **4**, wherein advancing a delivery device to a native mitral valve region via a left ventricle comprises inserting the delivery device into the left ventricle through an incision in an apex of the left ventricle.

* * * * *